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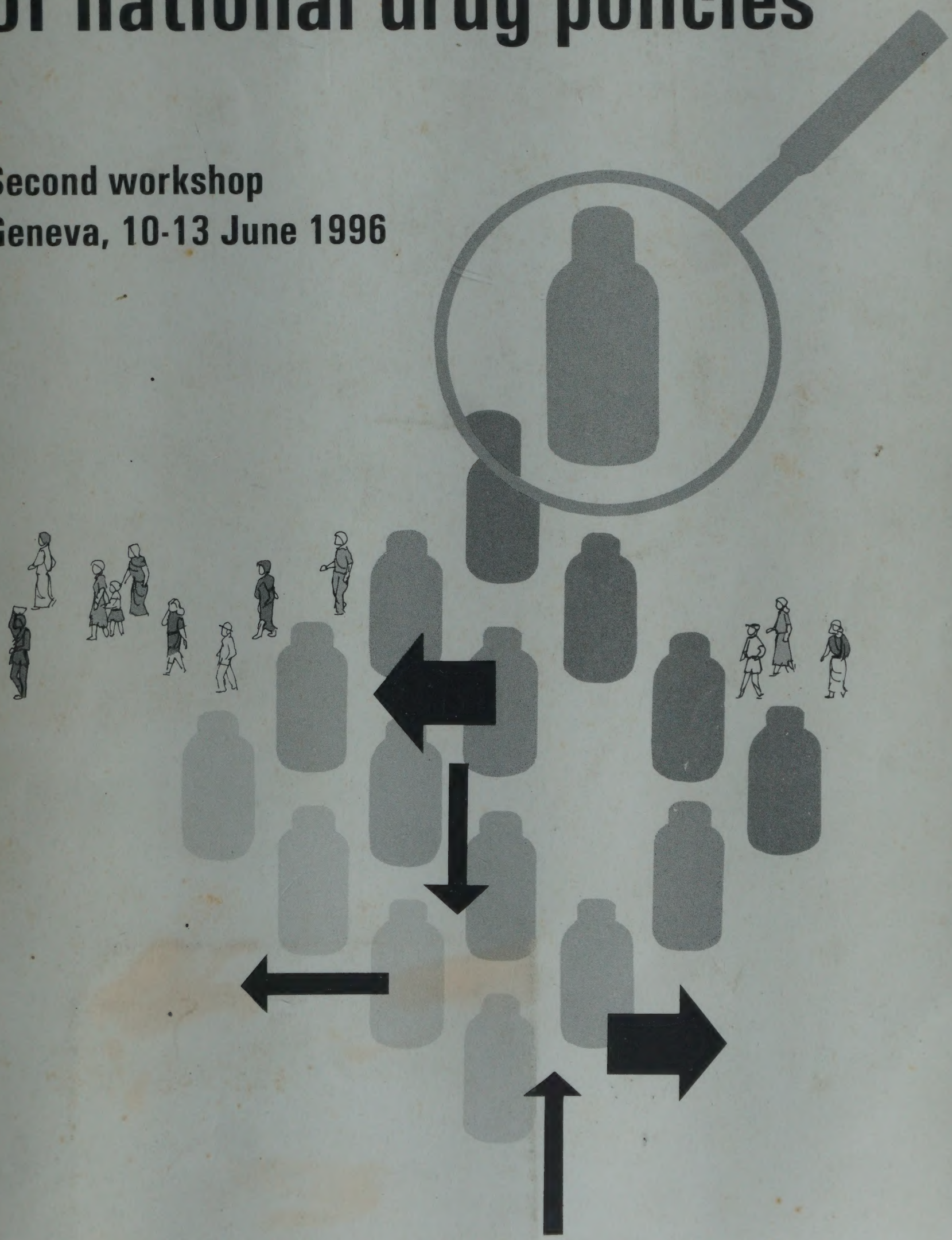
Comparative analysis of national drug policies

Second workshop
Geneva, 10-13 June 1996



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Comparative analysis of national drug policies in 12 countries

Second workshop
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Action Programme on Essential Drugs

Much research work, particularly in developing countries, at present goes unreported. The reasons for this include the intense competition to publish in the scientific press, and difficulties in matching the research resources of developed countries. The DAP research series was established to provide a forum for the rapid distribution of data and findings relevant to critical areas of drug policy and use. The Action Programme has a firm commitment to national operational research as part of its direct country support. It is also strongly committed to making the findings of such studies widely known and accessible. While every effort is made by the Programme to support studies of the highest possible quality, research skills and resources will vary from country to country. Documents in the DAP research series reflect this variation, and range from reports of very small scale studies, undertaken with minimal resources, to major global research involving substantive financial, scientific and editorial input.

This report has been prepared by Mrs Pascale Brudon (WHO Action Programme on Essential Drugs).

She benefited from the comments from all the participants in the workshop, mainly Prof. M. Reich (HSPH Boston) who prepared the paragraphs on political mapping, Ms K. Timmermans, who completed the consolidated tables in Annex 6 and reviewed the country data, Dr A. Reeler who took notes during the workshop, Dr G. Tomson and Dr T. Falkenberg (IHCAR), Dr J.D. Rainhorn (CREDES), Dr R. Govindaraj (HSPH, Boston) and from staff of the Action Programme on Essential Drugs. The researchers at country level (namely, Dr T.V. Benisheva-Dimitrova, Dr E. Carandang, Dr E. Gonzalez-Sedano, Mr M. Fofana, Mr M. Laloge, Mr M. Ndlovu, Mr L. Ngarmadjingaye, Dr Nguyen Thanh Do, Dr G.I. Petrova, Dr G.N.V. Ramana, Dr Sauwakon Ratanawijitrasin, Mr O. Sidibe, Mrs B. Trap, Dr K. Weerasuriya) reviewed the report before finalization and added useful insights.

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Executive summary

All countries in the world have national pharmaceutical policies, either explicit in the form of policy documents or implicit in government actions. Very few studies have been carried out which try to compare national drug policies and to understand which policies have been successful - and why - in achieving the goals of availability, accessibility, good quality and rational use of drugs. This document describes the preliminary findings of such a study as discussed in a workshop held in June 1996 in WHO, Geneva.

The comparative analysis of NDPs: Objectives and approaches

The objectives of the research were:

- to identify strengths, weaknesses, and political dimensions of pharmaceutical policy formulation and implementation within each country;
- to propose explanations for cross national variations in performance; and
- to propose effective strategies, both national and international, that can improve pharmaceutical policy implementation.

The research initiated by the WHO Action Programme on Essential Drugs in collaboration with the Division of International Health Care Research (IHCAR), Stockholm, and the Harvard School of Public Health (Boston) was conducted by national research teams in 12 countries (Bulgaria, Chad, Colombia, Guinea, India, Mali, Philippines, Sri Lanka, Thailand, Viet Nam, Zambia, and Zimbabwe).

To achieve its objectives, the research provided a cross national, comparative framework and combined formative evaluation strategies (focusing on the process of policy formulation and implementation) and summative evaluation strategies (focusing on policy outcomes). The two main research tools used were *standardized NDP indicators* - for assessment of NDP performance; and *political mapping* - for the analysis of NDP formulation and implementation processes.

The workshop and its main outcomes

The workshop described in the document was the third step in the implementation of this collaborative project. Its aim was to provide methodological support to the research teams, to review the results, to assess the two methods and to prepare a plan for the finalization and dissemination of the research findings.

The workshop:

- provided one of the first occasions for countries to compare data collected in a standardized way. It showed the importance of having good methods and data and justified the WHO strategy of providing standardized methods for both national assessment and cross national comparison;

- permitted the review of the indicators and the political mapping as methods of policy analysis and assessments of NDP (field testing) and resulted in some improvements which will be incorporated in the next edition;

- allowed countries to share experiences in order to develop better approaches for policy formulation and implementation. Although there is no standard recipe for improving the policy process in countries, the workshop did come up with some useful conclusions;

- began the process of identifying specific strengths and weaknesses of existing policy from national and cross national perspectives; of generating hypotheses to explain how different pharmaceutical policies can affect the performance of the pharmaceutical sector; and of identifying specific policy innovations;

- showed the necessity to develop such research in countries with different socio-economic backgrounds; and to set up sustainable NDP monitoring systems in most countries;

- finally, enhanced the research capabilities of all the participants of the 12 countries.

Preliminary results

The report reviews the main results of the research at this stage in relation to (i) the methods used; (ii) the national drug policies; (iii) the cross national comparison. These findings are preliminary as not all the country teams had finalized the collection and processed the data at the moment of the workshop.

Standardized indicators and political mapping

- The aim of the research was to use a set of standardized indicators to assess the achievement of the NDP and to use the political mapping technique to better analyse the process of policy formulation and implementation. During a previous workshop it was agreed that countries had the freedom to adapt or modify the indicators to better reflect their own country context. A set of common indicators should however be preserved given the comparative focus of the project. It was also suggested that a common mapping question related to the formulation process of the drug policy would probably further the process of comparison among countries. However it was decided that, given the different requirements of each country, they should be allowed to define their own questions for political mapping.

- A large percentage of the indicators was useful and did not need substantial modification. A few new indicators were constructed by country teams to better cover certain components of the pharmaceutical policy (e.g. in rational use of drugs). A number of new indicators was suggested for specific components or for additional objectives (e.g. traditional medicine). The main reasons for not applying certain indicators were the absence of data and the inconsistency in data at country level.

- Two countries used the political mapping to better understand what had happened in policy formulation and implementation and the reasons for successes and failures. One country used the political mapping to assess the chances of success of a new strategy to improve the affordability of the drugs in the private sector; the other countries looked at specific issues closely related to the components which had been assessed in the indicators' exercise.

- The two methods used in the research were relevant to assess the performance of a given national drug policy and the policy process. The various categories of indicators achieved their goals. The outcome indicators provided a good picture of the national situation in relation to the four objectives of the NDP. The structural and process indicators allowed the assessment of the level of implementation of the main components of the NDP. The indicators revealed new things on the policy and illustrated the importance of using certain types of data such as the financial data. They were helpful tools for focusing actions on deficiencies, and for finding solutions based on data and analysis. The method of political mapping helped policy-makers to systematically analyse the support and opposition for a proposed policy; consult with the major stakeholders on their views; analyse opportunities and obstacles to change; design a set of creative and effective strategies for change; and assess and track the processes of implementation.

Strengths and weaknesses of national drug policies

In most countries covered in the research, the systems/structures/mechanisms needed for effective implementation of a national drug policy were in place. However, they often did not function properly. Participants were able to identify strengths (e.g. established structures, comprehensiveness of the policy, etc.) and weaknesses of their country national drug policies (e.g. lack of implementation of rules, lack of concerns for financing and pricing issues, etc.).

In all countries there were components of the NDP which received more attention from decision makers and senior management staff; in most of the poorest countries these components were essential drugs lists and public procurement of drugs under INN. The situation was slightly different in middle income countries where the main components varied according to the objectives of the policy. Secondly, in all countries some things were easier to do than others: put the structures in place, improve the public sector, develop components not calling for drastic changes in behaviour, etc. Thirdly, it was difficult at this stage of the research to draw conclusions on the relative importance of each component in achieving the objectives of the NDP. Finally, there were linkages between components and between components and

objectives (e.g. absence of quality assurance system ⇒ poor quality of drugs, withdrawing irrational drugs ⇒ less irrational use of drugs, etc.).

In addition, the research clearly demonstrated that policy-making can not simply be a technical process but must also be a political process. Policy-makers need both technical and political analysis in order to be effective. Policy-making does not stop with the official adoption of a policy but continues on through the phase of implementation. Some common strategies may exist in national drug policies; it is however unlikely that a simple recipe exists for managing the formulation and implementation of all national drug policies. The approaches need to be developed and refined within specific national political contexts. They need to be adapted over time to fit evolving political circumstances and the problems that emerge in transforming the policy into practice.

Lessons from cross national analysis

The comparative cross national approach pursued in the research was valuable as, even at this very preliminary stage of analysis, it was possible to better explain the particular aspects of each country's policy and to identify more universal aspects of policy-making. The review of the variations among countries led to some tentative explanations, including:

- There was an obvious positive link between the performance of NDP and the economic development, although this did not apply for all the aspects of the policy.

- A number of technical components when implemented adequately made a great difference in terms of output: for instance a bad selection of drugs and an inefficient procurement system led invariably to shortages of drugs; on the contrary, a good registration system had a positive impact on rational use of drugs, a local manufacturing industry seemed to have a positive influence on prices of drugs as long as the country were big.

- Countries with no local industry (national or multinational) could implement the main aspects of NDP with fewer problems.

- Compulsory use of an EDL in the public sector was just a first step in improving availability and affordability. These objectives seemed more difficult to achieve in countries where the pharmaceutical market was mostly private and where there was no regulation of drug prices.

- The geographical situation of countries was also an important factor in the difference in performance, e.g.: to be an island was an advantage as it made drug imports easier to control.

- A few motivated people could make a difference between success and failure mainly to get things started, but to rely on only a few people was dangerous as it did not ensure sustainability.

- Improvements of the NDP through radical changes were more likely to happen when there were political windows of opportunity. When such opportunities presented themselves (e.g. new regimes) it was possible to implement quick, radical and widespread changes. When such opportunities were not available, it could be better to use a step-by-step approach.

- Technical soundness and/or economic rationality of a policy did not always imply that the policy was politically viable.

I. Introduction

Pharmaceuticals have made an important contribution to global reductions in mortality and morbidity. Making drugs available to the people and ensuring they are rationally used is, thus, a priority for every country. However, most countries confront a host of problems in their efforts to ensure the availability and rational use of safe and effective drugs. In trying to overcome these problems, many countries, mainly developing ones, have formulated national drug policies (NDPs) that specify national pharmaceutical goals and provide a framework for all parties involved. These policies have often been initiated with the assistance and active support from the Action Programme on Essential Drugs (DAP) of the World Health Organization (WHO), other bilateral and multilateral agencies and nongovernmental organizations.

Although such policies have been implemented by a number of countries, there has been no systematic effort to evaluate these policies on either a within-country or cross national basis. The project on "Comparative Analysis of National Drug Policies" was formulated to fill this lacuna. It was developed jointly by the Action Programme on Essential Drugs (DAP/WHO), the Department of Public Health Sciences, Division of International Health Care Research (IHCAR) at Karolinska Institutet (Sweden) and the Harvard School of Public Health (HSPH, Boston). The research took place in Colombia, Guinea, India, Philippines, Sri Lanka, Viet Nam, Zambia and Zimbabwe; all these countries were part of the original project. An additional four countries decided to participate in the research using their own funds (Chad and Thailand) or funds provided by the European Union through projects supported by the Centre de Recherche et d'Etudes pour le Développement de la Santé (CREDES), Paris (Bulgaria and Mali). The present workshop, which took place 10-13 June 1996 in Geneva, was the third step in the implementation of this collaborative project. It followed and built up on a series of meetings, workshops, and country work during which the research protocol was developed and the research was carried out by the different countries. The research is supported with funds from SIDA-SAREC and WHO/DAP.

This report constitutes five chapters and a series of annexes containing *interalia* data collected in the 12 countries. Following the introduction which provides a justification for the need for such research, the second chapter explains the objectives of the research, the main research questions and the methods used in the project. The third chapter describes the aim and objectives of the second workshop with the method of work. The fourth chapter, completed by Annexes 5 and 6, reviews the preliminary results in terms of the methods used and their relevance and outlines lessons learnt in relation to policy development and implementation. Finally, the fifth chapter gives the main conclusions and recommendations of the workshop.

II. Background on the research project

1. Research questions and objectives of the study

The overall goal of the research is to assess the performance of national pharmaceutical policies - focusing on policy process and policy outputs:

The principal research question that the project seeks to answer is:

> ***Have national drug policies (whether they exist as explicit policy documents, or are implicit in government actions) been successful in achieving the goals of availability, accessibility, good quality, and rational use of essential drugs? Why or why not?***

The specific objectives of the research are:

- to identify strengths, weaknesses, and political dimensions of pharmaceutical policy formulation and implementation within each country;
- to propose explanations for cross national variations in performance; and
- to propose effective strategies, both national and international, that can improve pharmaceutical policy implementation.

2. Study approach and research tools

The research provided a cross national, comparative framework. Cross national comparison can assist in placing a single country's experiences within a broader international context, and can help explain both the particular features of a country's policy and more universal aspects of policy-making.

The research combines formative evaluation strategies (focusing on the process of policy formulation and implementation) and summative evaluation strategies (focusing on policy outcomes). The two main research tools used are *standardized NDP indicators* - for assessment of NDP performance; and *political mapping* - for the analysis of NDP formulation and implementation processes. Group evaluation is also part of the methods used. These methods are described more in detail in the boxes below and in the research protocol (see Annex 1).

Method 1: Standardized NDP indicators

The indicators are derived from the WHO manual on *Indicators for monitoring national drug policies* (WHO/DAP/94.12). The indicators serve two purposes in the research:

- to assess the implementation of NDP by measuring progress in key components (structural and process indicators);
- to evaluate the outcomes of NDP (outcome indicators).

Background information	Structural indicators	Process indicators	Outcome indicators
Quantitative	**Qualitative**	**Quantitative**	**Quantitative**
Population data Economic data Health status data Health system data Human resources Drug sector organization	Legislation and regulation Essential drugs selection and drug registration Drug allocation in the health budget/public sector financing policy Public sector procurement procedures Public sector distribution and logistics Pricing policy Information and continuing education on drug use		Availability of essential drugs Accessibility of essential drugs Quality of drugs Rational use of drugs

Method 2: Political mapping

The use of political mapping has three main goals in the research:

- to assess the organizational and political determinants of the policy process;
- to help explain the strengths and weaknesses identified by the indicators; and
- to assist in identifying and assessing strategies to improve pharmaceutical policy implementation.

As described in the research protocol, the methodology has descriptive, explanatory, and prescriptive objectives: to describe the consequences, stakeholders, interests, and networks involved in the national drug policy; to help explain how and why a particular decision was reached in the past; and to assist decision-makers in managing the politics of formulation or implementation.

3. Project past activities

A number of activities took place before this second workshop. They included:

- A preparatory meeting of the project coordinators in Boston in September 1993 where a draft research proposal was discussed. It was agreed to prepare a background paper which would provide the theoretical foundations for the methods to be used in the project.
- The *background paper*[1] reviewed the existing literature on the evaluation of social programmes and this review was intended to: provide background information on the project's methodological framework for the comparative evaluation of pharmaceutical policies in developing countries; promote better understanding of key issues related to pharmaceutical policy formulation, implementation and evaluation, and provide materials that could assist in generating research questions for the project. The paper consisted of three main sections: on evaluation methods, on problems in the pharmaceutical sector, and on the formulation and implementation of pharmaceutical policy.
- The *research protocol* was finalized; this document was to be used by each country team to prepare its own country protocol (see Annex 2).
- The background paper and the research protocol were discussed and agreed upon by the three collaborating institutions in a meeting in Stockholm in March 1994. The countries where the project would be implemented were selected, and the formal roles and responsibilities of each coordinating institution with regard to the project in general and to each participating country in particular were agreed upon. The country team leaders were to be identified by the respective collaborating institution and to be agreed to by the Ministry of Health of each country. The eight countries selected for this project were: Colombia, Guinea, India, Philippines, Sri Lanka, Viet Nam, Zambia, and Zimbabwe. These countries from Africa, Asia, and Latin America were chosen based on the following criteria: socio-economic status, political system and regime type, geographical and demographic factors, colonial history, existence or absence of a formal NDP, public-private mix and size of domestic pharmaceutical industry, availability of in-country contacts, and the existence of previous studies. *They include some of the world's poorest countries, as well as some middle-income countries; countries with no pharmaceutical manufacturing capacity, as well as some with substantial capacity.*
- A *first workshop* was held in October 1994 in Geneva and was the first step in the implementation of the research and also the first round of group evaluation. Its overall goal was to formally introduce the project to the participating countries, initiate work on the individual country research protocols, strengthen the research capabilities of country teams by

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[1] Govindaraj, R. Pharmaceuticals and the formulation, implementation, and evaluation of drug policies in developing countries, WHO/DAP, May 1994 (unpublished document). The paper prepared by Dr R. Govindaraj (HSPH) is available on request in WHO/DAP.

providing training in the research methods to be used as part of the project and achieve group consensus on their applications. Research methods were presented and discussed thoroughly, draft country research proposals, and a plan for the future steps were prepared. The workshop was successful in achieving consensus on the methods to be used in all studies, thus enhancing the comparative nature of the research, leaving the country teams freedom to add to or complement these methods[2].

- The research was carried out by the eight countries with ongoing technical support from the three collaborating institutions. Some delays took place due to problems in transfer of funds, change in principal investigator, heavy workload of researchers at country level, etc. All the countries carried out the NDP assessment using standardized indicators; this work involved in each country a large number of people from different sectors and most of the time included national workshops on research methodologies and sampling procedures. Five countries out of the eight implemented the political mapping exercise (Colombia, India, the Philippines, Sri Lanka and Viet Nam); in India, the Philippines and Sri Lanka, the political mapping was undertaken with the direct technical support of the HSPH. A research team from Thailand decided to join the project and was able to carry out most of the NDP assessment and the political mapping. Three additional countries carried out the assessment of NDP using indicators: Bulgaria, Chad and Mali (see Table 1). *All country teams prepared draft reports with preliminary findings and most were able to present their findings to policy-makers.*

Table 1: Who has done what?

	Indicators	Political mapping
Bulgaria	✔	
Chad	✔	
Colombia	✔	✔
Guinea	✔	
India	✔	✔
Mali	✔	
Philippines	✔	✔
Sri Lanka	✔	✔
Thailand	✔	✔
Viet Nam	✔	✔
Zambia	✔	
Zimbabwe	✔	

[2] Report of a workshop on the research on comparative analysis of national drug policies, Geneva, 6-8 October 1994, WHO/DAP (unpublished document). The report of the workshop is available on request in WHO/DAP.

III. Second workshop

The workshop was the second round of group evaluation. It was held in Geneva from 10 to 13 June 1996, and organized and supported financially by the WHO Action Programme on Essential Drugs (DAP/WHO).

1. Aim and objectives

The aim of the workshop was to review the results of the different research projects, to solve methodological problems and to prepare a plan for the finalization and dissemination of the research findings.

The specific objectives were:

- To provide methodological support to the research teams in order to improve the research findings.
- To review the results in relation to the overall research objectives, namely:
  - to identify strengths, weaknesses, and political dimensions of pharmaceutical policy formulation and implementation within each country;
  - to propose explanations for cross national variations in performance; and
  - to propose effective strategies, both national and international, that can improve pharmaceutical policy implementation.
- To assess the two methods used in the research: standardized indicators and political mapping in terms of usefulness, reliability, ease of implementation, etc.
- To prepare a plan for the next steps, including the dissemination of the findings.

2. Participants

The workshop included 26 participants (see List of Participants in Annex 2):

- Researchers from the initial group of countries: Colombia, Guinea, India, the Philippines, Sri Lanka, Viet Nam, Zambia, and Zimbabwe.
- Researchers from countries which joined the research later and implemented the WHO Indicators for Monitoring National Drug Policies and/or the political mapping: Bulgaria, Chad, Mali and Thailand.
- Resource persons to provide technical support in epidemiology and statistics.
- Coordinators from the Action Programme on Essential Drugs (WHO), the Harvard School of Public Health, and the Karolinska Institutet (IHCAR).

Table 2: Background information on the participating countries

	Bulgaria	Chad	Colombia	Guinea	India[1]	Mali	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
Total population (in millions)	8.4	6.6	37.5	6.3	70.5	8.8	68	17.6	59	72.5	9.3	11.5
Life expectancy (years)	70.9	50.3	69	47	60.7F/57.3M	62F/59M[2]	65	75F/71M[2]	69.6	65	55F/50M[2]	61
GNP per capita (US$)	1186	169	1260	450	61	168	952	588	1650	220	350	438
Infant mortality rate (per 1,000)	16.3	145	27.3	136	60	103	56	17.2	25.95	46	123.3	61
Total public drug expenditure per capita (US$)	8.24	0.05	5.35	0.27	0.13	0.14	0.6	1.34	1.57[3]	0.46	na	4.49
Total value of international aid for drugs (cash + kind) (million US$)	0.2	5.2	0	na	0.02	4.8	na	0.5	na	7.2	na	9.25
Total value of local production (ex-factory price) **sold in the country** (million US$)	66.6	0.2	980	0	657.1	4.9	na	5.5	481.3	87	na	42.6
Total value of drug imports (CIF) (million US$)	29.44	11.6	20	na	na	11.7	171	50	187.3	152	na	44.7
Total number of pharmacies and outlets in the public sector (including health facilities and hospitals that dispense drugs)	1180	na	3250	399	1817	77	363	922	9648	22400	877	1037
Total number of pharmacies and drug outlets in the private sector[4]	2200	172	13000	199	14703	468	9985	1541	23842	19300	288	922

[1] Figures for one state (Andhra Pradesh) only

[2] F = female / M = male

[3] Ministry of Public Health only

[4] In many countries, the number of drug outlets is far above the number of pharmacies

Source: Data coming from the country research 1993-1994-1995 (see Annex 6)

3. Method of work and proceedings

The workshop was informal with a high degree of participation from country teams as well as facilitators. A large amount of preparatory work had been done by country teams and facilitators and the discussions reflected this (see Annex 3: Agenda).

The ***first session*** of the workshop was devoted to opening remarks by Dr F.S. Antezana, Assistant Director General, and by Dr J. Quick, Director of the Action Programme on Essential Drugs and to the presentation of the objectives and the agenda by Mrs P. Brudon, who was also the main coordinator of the research.

In his presentation, Dr F.S. Antezana pointed out that essential drugs were a corner stone of the 1978 Alma Ata declaration on primary health care and that the concept of essential drugs reflected the Organization's basic principle for equity. Today, in a time of global change, essential drugs and national drug policies were an important aspect of any health sector reform and he hoped that the present research project would come up with ideas and strategies on how to address changes at global and country levels.

Dr J. Quick, stressed the fact that 20 years ago only a few countries had national drug policies (e.g. Norway, Papua New Guinea, Peru, Sri Lanka). Today more than 60 countries have national drug policies and a few others were in the process of formulating a national drug policy. The research was therefore very timely. It would assist in better understanding how NDPs work and in addition it would allow assessment of the two methods used; Dr Quick felt that such multicountry research was the right approach for DAP. He believed that an important task would be to put the research results into practice and to ensure that ministries of health were fully involved in the discussions and dissemination of the results.

The ***second session*** was devoted to the evaluation of NDP performance through the application of the WHO indicators for monitoring NDP. The session had three main objectives: to share the experiences of the countries in carrying out the indicators' assessment, to solve any methodological problems encountered by the country teams in applying the indicators, and to discuss the method, the findings, and the analysis and interpretation of the findings.

The session included short presentations by countries on the ways they applied the indicators, the results (especially what they have learnt) and the main problems encountered. This was followed by comments and questions by two discussants and by a general discussion. The main features of these country presentations have been included in the relevant parts of Chapter IV. Working groups were then established to review methodological problems: one was looking at the sampling issues, the second one reviewed the methods to calculate a basket of drugs and the third one concentrated on indicators and suggestions to improve some of them. The groups assembled again in plenary and presented their recommendations. A review of the issues discussed can be found in Chapter IV. The last part of the session was allotted to preliminary discussions on the relevance of the indicators to assess each NDP, on the findings in terms of

policy achievements and on the analysis of the findings to better understand policy process. The conclusions of the deliberations are provided in Chapter IV.

The ***third session*** was devoted to political mapping. Each of the six countries which undertook political mapping presented its results and the problems encountered. This was followed by a group discussion on the results of the mapping exercise and its use in assessing policy process. More information is provided in Chapter IV.

The ***fourth session*** focused on what could be learnt at this preliminary stage on national drug policies through cross national comparisons and on the relevance of the two methods for cross national approach. Three working groups reviewed the results of each country and began to identify what works and does not work across countries, common patterns in policy implementation and factors which enable or prevent the formulation and implementation of successful NDP. They also assessed the usefulness of the indicators and the political mapping for international comparison. More specific comments are included in Chapter IV.

The ***fifth and concluding session*** discussed the next steps: time schedule for the preparation of the final country reports, strategies for publication and dissemination of the results, funding issues, etc. The main decisions agreed upon are summarized in Chapter V.

IV. Preliminary findings

This chapter reviews the main results of the research at this stage in relation to: (i) the methods used; (ii) the national drug policies; (iii) the cross national comparison and (iv) the broader process of capacity building. It should be noted that these findings are preliminary, mainly the ones related to national drug policies and cross national comparison, as not all the country teams had finalized the collection and processing of the data at the moment of the workshop and very few had undertaken a comprehensive analysis of the results.

1. The methods: What has been learnt?

Three main issues were discussed during the workshop in relation to the methods: their use by the country teams (see 1.1), the methodological problems faced by countries in applying them (see 1.2) and the relevance of the methods to achieve the objectives of the research (see 1.3).

1.1 Methods in context: How did the country teams use the methods?

The aim of the research was to use a set of standardized indicators to assess the achievement of the NDP and to use the political mapping technique to better analyse the process of policy formulation and implementation. During the first workshop it was agreed that countries had the freedom to adapt or modify the indicators to better reflect their own country context but that as large a set of common indicators as possible should be preserved given the comparative focus of the project. It was also suggested that a common mapping question related to the formulation process of the drug policy would probably further the process of comparison among countries; however it was decided that, given the different requirements of each country, they should be allowed to define their own questions for political mapping.

Methods in context: the NDP indicators

All the countries applied the indicators although some did not finalize the data collection and analysis before the workshop.

Four categories of modifications were introduced by countries in the initial list of indicators (see also Table 3):

- ***Introduction of new indicators:*** only four countries added new indicators; Chad introduced a number of background, structural and process indicators already available in the health information system and six new indicators related to the level of education of prescribers and dispensers; the type of suppliers for the public and the private sectors; the number of drugs received in the private compared to the public sector, and the percentage of children under five with diarrhoea that have been

prescribed ORS. Colombia introduced one additional indicator for rational use, namely the percentage of prescriptions dispensed in total by the hospital pharmacy. Guinea added eight indicators, four addressed more in detail rational use of drugs (WHO/INRUD indicators), the other four covered practices related to generics in the private sector. The Philippines added indicators on rational use (WHO/INRUD indicators) in health facilities and in drug outlets; it also created new indicators to compare the practices in the Government and in the private facilities in relation to compliance with the EDL and access to a drug formulary. Thailand added two indicators related to dispensing practices: percentage of drugs dispensed with a drug name on the label (N°1) and with instructions for use on the label (N°2). Although the team from Viet Nam did not introduce new indicators, they tried to use 24 indicators from the proposed ones to assess the implementation of the policy on traditional medicine and local production. A number of countries felt that for components that were already functioning well, more specific indicators may be needed to monitor improvements over time.

- ***Modification of existing indicators:*** three countries changed some of the indicators proposed; Chad modified three indicators because of lack of data for the past three years. Colombia did the same with three indicators to adapt to the national context characterized by a decentralization of key functions such as procurement of drugs. Zimbabwe modified 18 indicators to allow comparisons over time, to simplify calculations, because no data were available or to be consistent with previous surveys.

- ***Withdrawal of indicators because they were not relevant:*** a number of countries decided not to apply some indicators because they felt the indicators were not relevant to the country situation. For instance, Bulgaria did not apply the structural indicators related to the vehicles of the central procurement/distribution unit as such a unit did not exist (ST36). Colombia did not apply four structural indicators related to drug donations, centralized budget and procurement. The Philippines also excluded a few indicators, e.g. the indicator related to the provision of foreign currency to the procurement unit as all purchases are done internally (ST27). In general, the indicators which were not relevant refer to foreign exchange for buying drugs (Colombia, India, the Philippines buy internally all the drugs), to centralized structures (Colombia and the Philippines are countries where the decentralized process is very advanced); to local manufacture (Chad and Guinea have no local production), and to collection of drug samples (some countries like Zimbabwe have a policy not to collect samples on a routine basis).

- ***Withdrawal of indicators because data were not available:*** all countries encountered problems in obtaining data. India could not calculate three indicators because of the lack of data at national level on drug education or the lack of knowledge of the existence of international data (e.g. international lists of drug prices). Sri Lanka excluded some indicators such as total health expenditure (data not available) and the indicator related to banned drugs because the team felt the UN list of banned products was not appropriate for the calculation of this indicator. Viet Nam could not collect 11 data needed for process indicators on tenders, pricing, advertising and banned drugs. Guinea and the Philippines were not able to calculate some indicators as some data were not available.

Table 3: Changes introduced by countries in the proposed WHO list of indicators

Indicators / Countries	New indicators	Modified indicators	Background indicators		Structural indicators		Process indicators		Outcome indicators	
			NR	NA	NR	NA	NR	NA	NR	NA
Bulgaria	-	-	1	2	1	-	-	1	-	-
Chad	6	3	1	2	1	2	2	11	-	2
Colombia	1	3	-	-	4	-	-	-	-	-
Guinea	8	-	-	4	-	-	1	10	-	-
India	-	-	-	1	1	-	-	2	-	-
Mali	-	-	-	-	-	-	-	*	-	*
Philippines	5	-	-	2	2	4	-	18	-	1
Sri Lanka	-	-	-	3	-	-	1	7	-	1
Thailand	2	-	-	4	-	-	-	12**	-	**
Viet Nam	-	-	-	1	-	-	2	8	-	0
Zambia	-	-	-	-	-	-	1	*	-	-
Zimbabwe	-	18	-	-	-	-	1	1	-	-

* Data collection not yet finalized
** Did not carry out the total assessment
NR: Not relevant
NA: Not available

Methods in context: the political mapping

The subjects selected by countries for the political mapping were the following:

- ***Colombia:*** Identifying political statements considered essential for the full implementation of the NDP (prospective mapping).

- ***India:*** Explaining the changes in the formulation and implementation of the most recent NDP (1994-1995) compared to previous versions of the policy (retrospective mapping).

- ***Sri Lanka:*** Assessing the feasibility of getting a new drug pricing formula (NPF) enacted. Assisting policy advocates in designing and implementing appropriate strategies for the enactment of the NPF (prospective and prescriptive mapping).

- ***Thailand:*** Analysing the policy process in the development of the Generic Labelling and Advertising Policy (retrospective mapping).

- ***The Philippines:*** Evaluating the formulation and implementation phases of the Generics Act. Understanding the implications of the differences in the process and outcomes of these two phases of the policy for the future of the Generics Law (retrospective and prospective mapping).

- ***Viet Nam:*** Evaluating the formulation and implementation of the drug information policy (retrospective mapping).

Methods in context

NDP indicators: A high percentage of the indicators was relevant and useful to the countries situations and did not need substantial modifications. A few indicators were constructed by country teams to better cover certain components of the pharmaceutical policy (e.g. in rational use of drugs). A number of new indicators was suggested during the workshop for specific components or for additional objectives (e.g. traditional medicine). The main reasons for not applying certain indicators were the absence of data and the inconsistency in data. One country felt that some data were too sophisticated although useful for pharmaceutical systems in developing countries. However, it was agreed that data are often available but not easily accessible, mainly financial data which are collected in other departments than the pharmacy one.

Political mapping: Two countries used the political mapping to better understand what had happened in policy formulation and implementation and the reasons for successes and failures. It should be noted that the two countries in question: India and the Philippines have formulated a drug policy recently; this policy has very clear objectives and strategies, which makes a retrospective analysis easier. One country (Sri Lanka) used the political mapping to assess the chances of success of a new strategy to improve the affordability of the drugs in the private sector; the other countries looked at specific issues closely related to the components which had been assessed in the indicators exercise.

1.2 Methods in question: What were the main problems encountered and how to solve them?

It was the first time for most country teams that they applied the two methods of the research; it was also the first time that the two methods were used in such a large group of countries and within a comparative framework. It was therefore expected by the coordinators that problems mainly related to methodological issues such as sampling would arise during the conduct of the research, in spite of the training provided during the first workshop. Many of the problems were solved underway with the technical support of the coordinating institutions, some still remained unsolved for a few teams. This second workshop offered an occasion to review the main problems in order to improve the research results and to provide suggestions to improve the methods.

Methods in question: the NDP indicators

(a) Problems encountered

Five categories of problems were identified by the research teams

Methodological problems: A number of countries had difficulties in calculating the basket of drugs (India, Mali, the Philippines, Viet Nam) or

did not follow the method proposed in the manual (Guinea). The main reason was the lack of access to data on disease prevalence and drug consumption. It was also felt that the ways to estimate the average price of a basket of food could be described in more detail in the manual (India). For two countries, structural indicators could be made more specific and qualitative (Thailand and Zimbabwe) whereas for one (the Philippines) there was a risk of bias depending on the position of the researcher for the structural indicators. Also the pharmacy surveys could be biased (Sri Lanka) as the pharmacists know that they are surveyed.

Availability of data: All the teams had problems in obtaining some data, mainly the financial ones. In addition data were often incomplete (Guinea) or aggregated at levels different than the ones required in the indicators (the Philippines, Thailand and Viet Nam). In some cases, the reliability of the data was difficult to assess (Guinea, India, Mali, Viet Nam and Zimbabwe).

Collection of data: Some countries faced problems in collecting the data because of geographical and logistical difficulties (Chad, Guinea, the Philippines), because places to be surveyed were closed (Chad) or received too few patients to collect enough prescriptions in two days (Guinea). The collection of data is also time consuming as it involves visiting many different services (Mali) and training surveyors. "Even good training is not a guarantee of the quality of the surveys" (the Philippines).

Data processing and analysis: This can be complicated, entries need to be checked before encoding (Guinea, the Philippines). Analyses need to be done by knowledgeable people. In addition, another important point was to ensure that the chosen indicators really did measure the implementation and achievements of the policy. To establish clear links between the indicators and the implementation and impact of the policy was sometimes difficult (Zimbabwe). Most of the teams emphasized the need for a sustainable team to carry out the task regularly and to have the process incorporated into the regular activities (Mali, the Philippines, Zimbabwe). However, this is not always easy when financial and human resources are scarce.

Data presentation: The presentation of the results to the various target groups is not always easy; too many badly explained data do not attract attention. It was however not always feasible for the teams to present their data in a user friendly format, this was due to lack of time, lack of knowledge of some of the opportunities offered by the computers, etc.

(b) Suggestions to improve the method

The participants classified the problems they faced during the implementation of the indicator exercise in three groups: problems linked with the indicators themselves, sampling issues and calculation of the basket of drugs. The paragraphs below are the summary of the conclusions of each working group.

Working group on indicators: The group reviewed all the indicators and provided detailed comments on each category of indicators described in

the WHO manual. It was emphasized that before any move was made to use indicators, it was necessary to ask the question "What do we want to measure in relation to our policy? and why?".

For the background indicators, the group recommended to use data from the International Monetary Fund, the World Bank and national official publications as they provide reliability over time and facilitate comparison between countries. For data not available from these organizations, it is important to remember that it is not the "last" decimal which matters as the objective of these indicators is to provide the broad context and to identify trends. A number of suggestions to facilitate the applications of all the indicators were identified and presented at the plenary session.

Working group on sampling: The group reviewed the problems associated with sampling in the NDP surveys. It took the cases of the Philippines, Thailand, Viet Nam and Zambia as examples.

- *Sampling procedures:* The sampling procedures varied between the countries. In the Philippines, four regions of the country were selected. In each region, a sample of private and public facilities was drawn from lists available at the Ministry of Health. This sample seemed highly representative of the whole population. In Viet Nam, the sampling was slightly more complex, with selection of 6 provinces (3 in the North, 3 in the South; 2 including the two major cities, 2 representing the remote areas, and 2 representing the other areas). Again, the sample was most likely representative of the population. In Zambia, only two districts were selected, one in the North East, and the other in the South East, the most populated and economically active of the country. However, important parts of the country were omitted. This may introduce bias in the final estimates.

  There is obviously a trade off between the representativeness of the sample and the cost of the survey, which has to be taken into account. The statistical analysis of the results of the survey could provide information on the potential bias involved in the sampling techniques.

- *Choice of secondary units:* A critical issue is the choice of the secondary units. In general, investigators have stratified their samples along the lines indicated in the manual, that is : public hospitals (sometimes distinguishing between primary, secondary and tertiary hospitals), private hospitals, public drug outlets, private drug outlets, and remote health facilities. Viet Nam selected public hospitals, public drug outlets at district level and private drug outlets at provincial level. Investigators noted that two other types of secondary units could have been included : black markets, and private medical doctors who are allowed to sell drugs to their clients.

- *Choice of observation units (data sources):* Another critical issue for the validity of the studies was the choice of the observation units. It was recommended to use a sample of prescriptions. However,

in Thailand, investigators working on one of the samples in Bangkok had preferred to use "transactions" rather than "prescriptions". A transaction is a real negotiation between a client and a drug provider. In some places, transactions without a prescription may account for two-thirds of all drug purchases in the private drug outlets, even for antibiotics. Drug use in "transactions" (roughly self medication) may be quite different from drug use in "prescriptions" (normally with proper medical advice).

In one case (Zambia), the investigators added a household survey. This was considered important, since the most critical problem in this country was access to drugs. This seemed a valuable addition to the recommended strategy.

- *Other issues:* In Thailand, a "surrogate patient survey" was also conducted. A surrogate patient is a field worker or research assistant who visits health providers and presents them with fictitious case scenarios, then records the information. The method offers a chance to record non-self-conscious current practice from a point of view of the client in a first hand and standardized fashion. However, this approach may lead to bias if the field worker is not well prepared, and should not be recommended unless carefully planned. A participant also noted that this may raise serious ethical issues.

Working group on basket of drugs: Calculating the basket of drugs was a problem for some of the research teams. Bulgaria did it according to the manual and were helped by the existing statistical database. The group thought that without such a statistical backup (data on prevalence and consumption) most countries would find it difficult to calculate the basket of drugs. However it was agreed that the method proposed in the manual was the best one and should be used where possible. The group suggested alternative methods which may be used when the method proposed in the manual was not applicable. The alternative methods should be submitted to a limited group of experts for validation and if relevant should be included accordingly in the new edition of the manual. It was also thought that the explanations of the proposed method in Part IV of the manual could be improved in terms of clarity.

Methods in question: the political mapping

The political mapping analysis was applied in six countries: Colombia, India, the Philippines, Sri Lanka, Thailand, and Viet Nam. This lack of complete application in all the study countries suggests that problems existed either in the training provided for the method, or in the technical support provided by the coordinators. In addition, the six country teams encountered some problems inherent in the method of political mapping, as a form of applied political analysis for examining policy-making processes. The second workshop discussed several of these problems and limitations.

(a) Problems encountered

Technical support: The three countries that did not apply the method of political mapping had found that they did not have sufficient expertise within the country team to learn the new method. In some countries, the team may not have included persons with training in policy analysis or social science, which usually helps with a political mapping analysis. In other countries, the lack of adequate computing facilities may have contributed to lack of application. The political mapping method uses a Windows-based software program and requires a 486 level processor. Technical support from the coordinators could have assisted in applying the political mapping method in the three countries that did not complete this analysis.

Quality of data: The political mapping method requires excellent data and knowledge about the basic policy-making processes for a specific decision. In the six countries where an analysis was performed, these data were collected through interviews with stakeholders. An inherent limitation of the political mapping method is assuring the quality and validity of the qualitative data collected through interviews. For this purpose, the study team performs an important role in discussing and assessing key judgments about players, their positions, their power, and the likely impacts of different political strategies. As with other policy analysis methods, political mapping is subject to the limitation of "garbage in, garbage out." The quality of the data affects the reliability of the analysis.

Collection of data: The six countries that performed the political mapping analysis initially expected some difficulties in the collection of data. Most countries, however, did not encounter difficulty in obtaining interviews with key decision-makers involved in the policy. Government officials and industry executives agreed to participate in the study and were, according to country reports, relatively open in discussing the policy decisions and the related processes. Accordingly, the collection of data was not a major problem for the political mapping analysis.

Data processing and analysis: The six countries reported a number of challenges in carrying out the data processing analysis in the political mapping. Several countries noted that the data analysis requires excellent knowledge about the policy among team members, and also a "good balance" within the team. One way of assessing the reliability of qualitative data about policy-making processes is through group discussion and collective judgment. For these methods to work well, the group needs to be able to function well together and to contain different kinds of expertise, both technical and political. Finally, the country teams also reported that the method cannot eliminate some unpredictable elements in policy-making processes.

Data presentation: Overall, the six country teams found the computer software to be an effective method for presenting the results of the political mapping analysis. However, the user still needs to exercise judgment in deciding which elements of the analysis should be

emphasized and which strategies should be recommended to decision-makers. In short, the method of political mapping does not replace analytic thinking or policy judgment. Finally, in a rapidly changing political environment, it may be necessary to update the analysis and the results on a regular basis, otherwise the analysis could be limited by specific circumstances. This time-specific dimension is an inherent limitation of the political mapping method.

(b) Suggestions to improve the method

Technical support: The participants agreed that it would have been possible to perform the political mapping analysis, if additional technical support had been provided to the three countries that did not carry out this part of the research project. Often, an external consultant, working with a national expert, can create an effective team of "outsider and insider," which is helpful both in collecting and assessing data related to policy-making processes. External consultants can also help in interviewing some government officials or industry executives, and in asking sensitive questions about policy-making processes.

Training: The participants suggested that additional training on the political mapping method, using the updated version of the computer software (Policy-maker 2.0) would help with future efforts to perform a political mapping analysis. New help texts and tutorials, which are now being prepared, are also expected to assist first-time users in applying the software and carrying out a political mapping analysis.

Language: It was also suggested that the political mapping software and manual could be translated into French, in order to make the method more accessible to French-speaking countries. The current materials are available only in English.

Selection of policy for analysis: The participants suggested that the selection of the issues for analysis is a critical factor in carrying out political mapping. The analysis seems to work better for well-defined issues and policies, in both data collection and data analysis phases.

Methods in question

NDP indicators: The main problems faced by research teams were related to issues such as sampling, basket of drugs and difficulty to obtain reliable data; the teams however agreed that the methods proposed in the WHO manual on indicators including the sampling ones were well described and practical. They recommended that the suggestions made during the workshop be taken into consideration when revising the manual. In addition, DAP will provide in a separate document or in the next edition of the manual, practical information based on the results of the application of the indicators in the 12 countries.

Political mapping: Main problems encountered by the teams were related to the quality of the data (as other policy analysis methods, political mapping is subject to the limitation of "garbage in, garbage out"); and the data analysis. The data collection was easier than expected and the computer software was an effective method for presenting the results. The participants suggested additional training on the political mapping method.

1.3 Relevance of the methods

When defining the research objectives and questions, the coordinators of the project selected the WHO set of indicators for monitoring NDP and the political mapping as the two best methods for obtaining the answers to the questions raised. It was therefore important to review during the workshop the relevance of the research: Were the country teams able to assess NDP performance with the indicators and the policy process with the political mapping?

Relevance of the NDP indicators

The participants reviewed the capacity of the indicators:

- to assess the level of implementation of the NDP,
- to evaluate the outcomes of the NDP,
- to reveal new aspects of the policy, unknown facts and realities.

A questionnaire was prepared by the facilitators and used by the country teams to support this process (see Annex 4). The main preliminary conclusions of the workshop can be summarized as follows:

(a) Assessing the structures and processes of the NDP

All the country teams found the two categories of indicators (structural and process) *useful to assess the implementation of the various components of the NDP* (see page 4) and identify areas that need improvement. Structural indicators were easy to collect. Most countries collected between 92% to 100% of them. Countries had more problems to calculate process indicators; however, with the exception of

countries which had not finalized the study at the moment of the workshop (Mali, Zambia) and countries which decided not to collect all the indicators (Thailand), countries were able to calculate between 55% (the Philippines) and 94% of the process indicators (Bulgaria, India and Zimbabwe). For Zimbabwe "the quantifiable indicators gave an assessment of the degree and trend of the implementation. Further as Zimbabwe had most data available for 1993-1995 it strengthened the evaluation of the implementation". Bulgaria was also able to assess the performance of NDP, the same applies for Guinea, India, the Philippines and Viet Nam. Colombia could assess the implementation of the NDP except in the area of financing of drugs as there was a shift from traditional funding to public facilities with fiscal revenues to insurance. For the time being, there was not enough available data during the period of transition to properly assess this component. Sri Lanka felt also that the indicators work better for some areas than for others. Viet Nam stressed the fact that the indicators point out the lack of some important activities and strategies which need to be developed such as tenders and drug policies, and problems but not the reasons for these problems; it is also often difficult to know what is the ideal value of an indicator. Finally, Colombia partly supported by Viet Nam and Zimbabwe, felt that although the main aspects of the NDP were covered, it was necessary to have specific indicators on the implementation of the NDP in the context of the health reform. They should measure:

- The performance of the health authorities (at national, regional and local level) in a decentralized context.
- The performance of the health resources administrators (health plans, insurance) to use efficiently the per capita expenditure allocated in the system.
- The structure and process in the management and technological development of pharmaceutical services.
- The performance of the academic sector in function of the professionalization and qualification of human resources needed in the pharmaceutical sector; and provision of funding and technical assistance for the modernization of public sector procurement procedures, distribution and logistics (drug selection, programming, marketing, reception, storage, distribution and dispensing).
- The structure and process of the quality of the pharmaceutical care services: user's satisfaction, professional competence, security and continuity of care.

(b) Evaluating the outcomes of the NDP

All the country teams calculated most of the outcome indicators included in the WHO manual; Guinea, India and Viet Nam calculated the 10 outcome indicators; the Philippines and Sri Lanka could not calculate one indicator, different in each case; Thailand was able to collect only a few indicators, however as said earlier the Thai team did not perform the indicators study in full. Most countries felt that the 10 indicators provided a good measure of what the situation was in relation to the four main objectives of a policy, namely availability and accessibility to essential drugs and quality and rational use of drugs. For Zimbabwe, "the indicators give a good overview and it is easy to include additional specific national indicators". For India "considering the inputs used, the results are quite rewarding". For Chad and Mali the indicators provide

"good baseline data which will allow to look at progress". A few countries felt that some additional outcome indicators — quality of pharmaceutical care and coverage of the social security system in relation to the total population in Colombia, self-medication in the Philippines — would have been useful to evaluate better the four objectives: Guinea and Viet Nam which added a few indicators on patient care and RUD felt that this "helped to get a more precise idea of the outcome of the policy".

Most countries would have liked more outcome indicators for additional objectives of their policies: traditional medicine was the most frequent missing objective (Chad, Guinea, Mali, the Philippines, Thailand and Viet Nam) followed by self-reliance and domestic industry (Bulgaria, India, the Philippines and Thailand) and by illegal market (Chad, Guinea, Mali, Thailand and Viet Nam). Guinea, the Philippines, Viet Nam and Zimbabwe would welcome some additional indicators for rational use of drugs at patient and community levels including indicators on standard treatment guidelines.

(c) Discovering new aspects of NDP

Through the assessment of the performance of the NDP using the different categories of indicators *all the country teams found things they and their policy-makers did not know or expect*. For instance, Bulgaria, Chad, Mali, Viet Nam and Zimbabwe discovered that the area of *drug pricing was not receiving enough attention*. Colombia "had a general idea about what was going on but the usage of the indicators allow them to have a systematic approach to specific components of the policy and have a much clearer picture of the present stage in the implementation of the NDP"; the same applies for the Philippines, Sri Lanka, Viet Nam and Zimbabwe. Guinea discovered that *use of drugs was better* than expected and quality worse, that the cost of a prescription has not changed during the last three years at least in the capital, that the average cost of a prescription up country was 50% lower than in Conakry and that some wholesalers supply also the illegal market. In India it was noted that the increase in the price of the basket of drugs was linked to the New Drug Price Control Order and that *the quality of the drugs in the basket was comparatively poorer than the quality of drugs in general*; this seems to reflect a shift in the practice of the industry, the essential drugs under generic name being left for production to small manufacturers, not all of them enforcing GMP. In Mali, it showed that prices decreased in the public sector mainly due to a new and *improved procurement sector*. In Sri Lanka the study demonstrated *the lack of information and data* on key areas and specific issues. There was a general belief "that something done upstream would have some influence downstream: pharmacies are registered and were therefore assumed to be not breaking the law too much. Surveys showed that this was not true and the rules were being broken much more than it was assumed. The Government has produced a Sri Lanka Hospital Formulary and made available sufficient copies for distribution to the prescribers in the State Health Sector. However, problems in the distribution system at the various levels meant that only a small minority of the prescribers had the formulary available with them". Zimbabwe learnt that the drug policy needs to be realistic and *more efforts should be devoted to priority setting*, that there should be a continuous development of the indicators and that the data collection system should be simple and sustainable. In Viet Nam, it showed also the lack of information and data, the problems of enforcing regulations and the *difficulties to adapt to market economy*.

Relevance of the political mapping

Three main aspects of the political mapping were discussed by the workshop participants: the nature and quality of the political mapping analyses that were performed, the findings and interpretations of the analyses, and an assessment of this method's ability to achieve the broader objectives of the research project. The participants identified the following ways in which the political mapping method contributed to an analysis of policy-making processes for national drug policies:

Systematic political picture: The method provided a systematic assessment of the political environment in which a national drug policy is formulated and implemented. At a minimum, the analysis provided a description of the political dimensions of a policy decision, and a method to organize the multiple dimensions of a complex decision. One country team reported that they had not previously considered the political dimensions involved in implementation of a national drug policy.

Assistance in strategy design: For those countries actively considering policy changes and therefore engaged in a prospective political mapping analysis (Colombia, the Philippines, Sri Lanka, Thailand and Viet Nam), the analysis provided practical assistance in the design of political strategies. The systematic political picture and the strategy suggestions (included in the software) were reported to be particularly helpful in designing strategies by some countries.

Challenge to assumptions: One team reported that the political mapping method was useful in making explicit the team's assumptions about how a new policy would be adopted and in forcing the team to explain and justify those assumptions. This process of questioning helped to enhance the coherence and feasibility of the policy. The analysis thus allowed the team to reflect on some of the unstated assumptions about how a new national drug policy would be accepted.

Reality testing: One team found the interviews to be particularly useful in checking the team's perceptions about other stakeholders. This advantage has been reported in other instances of political mapping analysis, and is one of the strengths of this method. The analysis helps to present a policy decision from multiple perspectives, and helps the country team view a problem from the perspectives of other stakeholders.

Team building: The process of performing the political mapping analysis helped create a sense of common language and sense of mission for some country teams. The analysis encourages the teams to rethink their strategies, taking into account the interactions among policies, players, and positions. Finally, the process was thought to strengthen the team's capacity to advocate for a national drug policy.

Relevance of the methods

NDP indicators: The participants agreed that the various categories of indicators achieve their goals, i.e. the outcome indicators provide a good picture of the national situation in relation to the four objectives of the NDP, the structural and process indicators allow the assessment of the level of implementation of the main components of the NDP; the indicators reveal new things on the policy and illustrate the importance of using certain types of data such as the financial data; finally, they are helpful tools for focusing actions on deficiencies, and for finding solutions based on data and analysis. The results of the exercise could also be used to achieve political consensus on the national drug policy. Most countries recommended that such collection of data should be undertaken regularly and budgeted in the MOH budget. There should however be a balance between the advantages of having good indicators but which are difficult to calculate and the amount of effort and cost needed to collect related data. In addition, the workshop recognized that it is difficult to focus on monitoring of NDP when the society as such is without "a culture of monitoring". The findings and lessons from the analysis are discussed below (in sections 2.1 and 2.2).

Political mapping: Workshop participants agreed that political mapping was a new and effective tool that could assist in the analysis of policy-making processes and in the design of strategies for both the formulation and implementation of national drug processes. While the method has a number of inherent limitations and application difficulties (discussed above in section 1.2.2), workshop participants believed that they had learned important insights from performing the analysis in their country. Overall, the participants concluded that the method of political mapping helps policy-makers to systematically analyse the support and opposition for a proposed policy; consult with the major stakeholders on their views, analyse opportunities and obstacles to change; design a set of creative and effective strategies for change; and assess and track the processes of implementation. The substantive findings and lessons from the analysis are discussed below (in section 2.3).

2. National drug policies: what has been learnt?

The main aim of the research was to assess if national drug policies (whether explicit or implicit) have been successful in achieving availability and accessibility to essential drugs, quality and rational use of drugs and to understand why and why not. The participants therefore reviewed the data obtained from the indicators and the information provided with the political mapping. As the data were not completed for all the countries and were not available to the coordinators before the workshop, it was not possible to go into detail in all these aspects; however, some preliminary analysis and interpretation

of results could be made which opened exciting avenues for the next steps of the research. These preliminary results are presented separately for the indicators and for the political mapping as they were discussed separately during the workshop.

2.1 Preliminary findings based on NDP indicators

To facilitate this discussion, the group used a questionnaire (see Annex 4).

(a) Assessing the implementation of NDP

The participants assessed broadly the seven main components of a NDP (see Annex 5 and Annex 6), as it is assumed that if these components were functioning properly, the objectives would be achieved. For most countries, the *structures/systems/mechanisms as measured by the structural indicators were in place.* For example, in all the countries there is a drug regulatory authority whose mandate includes registration and inspection (ST4); in all countries except Chad and Viet Nam, drugs in the public sector are usually procured through competitive tender (ST24). However, the weakest components everywhere are the ones related to financing of drugs in the public sector and pricing of drugs in the private sector. For example, only in five countries was the public drug expenditure per capita more than US$ 1.00 per year for the last three years (ST20).

In most countries although structures are in place, *implementation is not always working* as expected. As stated by the Guinean team "it is easier to create structures than to make them work". In the same country for example 87% of the drugs prescribed in the public sector were on the essential drugs list, the same figures from the private sector and the black market were 28% and 39% respectively. Zimbabwe provided an opposite example: for the public sector procurement procedures, the process indicators were better than the structural indicators. Although not all the structures are in place, Zimbabwe obtains very good prices for drugs, due to the fact that there are a few very knowledgeable and motivated staff at the procurement level.

Through this assessment, the countries were able to identify areas that need improvements, for example Zimbabwe identified the following issues: lead time for tenders, private procurement, inspection, information on adverse drug reactions, supervision, accounting and finance procedures.

(b) Achieving the objectives of NDP

The four objectives of most NDP: availability and accessibility of essential drugs, quality and rational use of drugs were assessed using a rating system from 1 to 5 based on the results of the 10 outcome indicators (see Table 4, Annex 5 and Annex 6 which also contain some explanations of the methods used for the rating). *Availability of essential drugs* (OT1 and 2) *was quite good in most countries* with the exception of Zambia. In the case of the Philippines, the availability was low mainly in the public sector. As these indicators take into account only a very limited basket of the most essential drugs, even a rate like 3 is not a very satisfactory result. The picture in terms of *accessibility to essential drugs is slightly less impressive;* in many countries the situation mainly in the private sector is not good (Bulgaria, Guinea, India, the Philippines and Viet Nam). *Quality of drugs*

remains an important problem in the poorest countries (Chad and Guinea) but is also not very good in countries like India, Thailand and Viet Nam. For example, in this last country 25% of the samples failed quality control tests. Finally, *the rational use of drugs is very rare with some countries performing better* (the Philippines, Zimbabwe). For instance in India 66% of the prescriptions surveyed in the public sector contained at least an injection; in Thailand the percentage of children receiving antidiarrhoeals from private drugstores was 96%.

Table 4: Achievement of the objectives of NDP - Preliminary results

	Availability of essential drugs	Accessibility of essential drugs	Quality of drugs	Rational use of drugs
Bulgaria	4	2	3	3
Chad	3	3	1	3
Colombia	4	4*	4	3
Guinea	4	4 (pub) 2 (priv)	2	3
India	3	2	2	1
Mali	3	-	-	2
Philippines	3	3	4	4
Sri Lanka	5	4	3	3
Thailand	-	-	2	1**
Viet Nam	4	3	2	2
Zambia	2	-	-	2
Zimbabwe	4	4	3	4

* Colombia: this figure is for people covered by the social security system (17.7 million people out of 37.5 million).

** Based on data from private drugstores.

1 = low achievement

5 = high achievement

(c) Reviewing strengths and weaknesses of NDP

Each participant identified the strengths and weaknesses of his/her country NDP through a broad analysis of the results of the indicators. It should be stated again that it was a preliminary analysis which will be refined once all the data will be reviewed and validated. For some countries the main strength they discovered was the fact that there are well *established structures*: legislation (Bulgaria, Chad, Colombia, Mali), quality control systems (Viet Nam), procurement procedures (Mali), distribution and logistics systems (Bulgaria), reliable health data (Bulgaria), well accepted EDL (Mali, Viet Nam); for others, the most important strength of the policy was its *integration in broader health and economic policies* (Colombia, Thailand, Zimbabwe). For instance "the main strength of the Colombian NDP is its inclusion in the context of the System of Social Security established in the country with the health reform. It provides a good structure for components related with legislation and regulation, essential drugs selection and drug registration, and drug allocation in the health budget.

These components of the policy are working quite well in terms of process for the population already covered by the Social Security System". For the Philippines, the main strengths were the *comprehensiveness of the policy* involving all stakeholders and the fact that the NDP programme is officially integrated in the Department of Health.

For many countries, weaknesses of the NDP include lack of implementation of rules and regulations (Bulgaria, Chad, Colombia, Guinea, Mali, the Philippines, Sri Lanka, Thailand and Viet Nam); no real commitment to monitoring including strengthening of data collection (Mali, the Philippines, Sri Lanka, Viet Nam and Zimbabwe); not enough concerns for financing and pricing issues (Bulgaria, Zimbabwe); lack of financial resources (Chad, Guinea, Mali, Viet Nam); and low emphasis on continuing education and training in RUD (Bulgaria, Colombia, India, Mali, Sri Lanka and Viet Nam).

National drug policies: what has been learnt?

NDP indicators: The results of the indicators, when carefully analysed, provided very useful information on the achievements of the policy and its main characteristics. Not only did they allow the assessment of the present situation but also the identification of areas needing further action and areas progressing well. In most countries, the systems/structures/ mechanisms were in place; however, they often did not function properly, which impeded implementation of strategies and policies and achievements of objectives. At this stage of the analysis it is however too early to assess the current link between structure and process indicators on one side and outcome indicators on the other side, although a careful examination of Annex 5 can show evidence of this. Participants were able to identify strengths (e.g. established structures, comprehensiveness of the policy, etc.) and weaknesses of their country NDP (e.g. lack of implementation of rules, lack of concerns for financing and pricing issues, etc.). A number of participants felt that the use of the indicators to monitor national drug policies should be supported by WHO and by other agencies at country level.

2.2 Preliminary interpretations based on NDP indicators

A number of hypotheses were made at the beginning of the research on the policy process in order to better understand why things work or do not work. These hypotheses were based on a review of the literature and on the experience acquired by the collaborating institutions in the field of drug policies. The hypotheses are related to the implementation of the key components, and cover issues such as speed and easiness of implementation; importance of the various components and links between components (for more details, see questionnaire in Annex 4). The following paragraphs are based on the discussions during the workshop and the results of the indicators.

(a) Are there components which have received more attention?

In all the countries there are components of the NDP which have received more attention than others and have been implemented first. For instance, in Chad, Guinea, Sri Lanka and Zambia, the essential drugs list, the improvement of the drug procurement in the public sector and the strengthening of the regulatory aspects (inspection, registration, legislation) have received more support than the other components. In Colombia, the development of the pharmaceutical care services has been the main purpose of the policy. Priorities to reach this goal were set as follows:

availability of drugs ➨ accessibility ➨ quality ➨ rational use

Therefore, the components which received more attention in Colombia were: legislation and regulation; essential drugs selection and drug registration; drug allocation in the health budget; pricing policy.

In India, the pricing issues were the ones receiving more attention because of the pressure of the industry and the GATT agreement. In the Philippines, while availability and affordability were main objectives of the policy, limited public funds and the difficulty of dealing with the economics of pharmaceuticals prevent strong action in this field. The quality assurance aspects (strengthening of the Bureau of Food and Drugs) received more attention, probably because the main actors of the NDP were closely linked to BFAD. Rational use of drugs was also the focus of a large number of activities. On the contrary, although only drugs on the EDL can be procured in the government sector; nothing really substantial has been done in terms of improving public procurement procedures including quantification of drugs needs. In Zimbabwe, legislation, essential drugs selection, drug distribution in the public sector received priority; this was linked to the priorities decided by the National Drug and Therapeutic Policy Advisory Committee and to the fact that financial and technical resources were available for these activities. Viet Nam focused on improving quality assurance systems including registration, legislation and regulations.

Based on these first findings, it seemed that in *most countries the improvement of the availability of essential drugs in the public sector through proper selection, good procurement and distribution has been given priority*. However, two middle income countries, India and the Philippines, which have developed very comprehensive and different drug policies behaved differently: one has favoured the issue of pricing due to the fact that one of the main objectives of the Indian policy is to strengthen the domestic pharmaceutical industry; the other has implemented first the components related to quality because the main technical people involved in the policy were "quality people" and policy-makers and because the policy aims to expand the coverage through the use of generic drugs in the private sector.

(b) Are there components which were easy to implement?

In all countries there are things which are easier to do than others. First the structures are relatively easy to set up (EDL, drug regulatory authority, procurement mix) but in many cases because of lack of resources, things do not function very well (Guinea: "the international aid is willing to support the establishment of central medical stores but the operating costs for supervision - fuel ... - are very difficult

to finance"). Secondly, components related to activities of the private sector are less easy to implement (Guinea, Thailand, Viet Nam). Thirdly, components which involve important changes in behaviour like improving use of drugs are also difficult to implement; in addition, they require collaboration between the Ministry of Health, the Ministry of Higher Education, district and local health authorities, the social security systems when they exist, medical associations and the academics (Colombia, Mali, Sri Lanka and Viet Nam). Finally if the policy is seeking drastic changes and is implemented on a large scale, it is always difficult to think in terms of linear progress, things can work at a moment because of strong political support and deteriorate later when the context changes (the Philippines).

In countries with strong decentralization like Colombia and the Philippines, the extent to how easy or difficult it is to implement a component is related mainly to the extent of governance of the Ministry of Health over each component and its operational capacity for implementing each component in a decentralized context. In Colombia, the Ministry of Health has governance for structuring the following components: legislation and regulation; essential drugs selection and drug registration; drug allocation in the health budget and pricing policy. However, because of the decentralization context, implementing those components (process) requires participation of district and local health authorities. So, the governance is shared heavily with the district and local governments, a process which is not easy, due to their poor operational capacity.

(c) Are there components which have been more important for achieving the NDP objectives than others?

Bulgaria, the Philippines and Thailand felt that all components were important, if one component was developed more than another "success will be temporary". Zimbabwe stated that the components should be developed all together but for each of them there are basic activities which need to be carried out and "you need at that level to make priorities". In Sri Lanka "since the state dominates the health care sector, public sector procurement made a bigger impact on achieving the two objectives of essential drugs availability and accessibility". In Guinea it seemed that improvement of diagnosis and prescribing practices in the public sector led to a general improvement of use of drugs. In Viet Nam the reorganization of the system and the improvement of management had positive effects on the drug situation. It was also realized by the teams that one cannot expect pharmaceutical systems to be functioning better than the health care system as such, although they may in some cases show the way (Sri Lanka).

(d) Are there any linkages in performance across components?

Although most countries agreed that *there are clear linkages between components and between components and objectives*, the issue was not thoroughly discussed as the results have not yet been fully analysed by the teams and the coordinators. However, a few obvious linkages were noted: absence of quality assurance system and low quality of the drugs on the market (Guinea), use of generic drugs in the public sector and low cost of treatment compared to what is happening in the private sector (Chad); withdrawing irrational drugs (no paediatric formulation of antidiarrhoeals) meant less irrational use (Sri Lanka); good public sector procurement influenced private sector (Sri Lanka); good quality of drugs

meant better acceptance of generic prescribing and dispensing (Thailand); using tenders meant increased availability of drugs, improving training influenced rational use of drugs (Zimbabwe). In Guinea there was no linkage between information and continuing education which performed very badly and rational use of drugs which was quite good; as said earlier it seems that prescribers in the public sector were well trained and influenced practices in the private sector. The same remark applied to Zimbabwe where despite continuous training, stock management has not improved. This of course lead to questions on the best strategies to improve practices and on the content of training.

National drug policies: preliminary interpretations

NDP indicators: In all countries there are components of the NDP which have received more attention; in most of the poorest countries these components are essential drugs lists and public procurement of drugs under INN. The situation is slightly different in middle income countries where the main components are not the same in all the countries and vary according to the objectives of the policy. Secondly, in all countries some things were easier to do than others: put the structures in place, improve the public sector, develop components which do not call for drastic changes in behaviour, etc. Thirdly, it is difficult at this stage of the research to draw conclusions on the relative importance of each component in achieving the objectives of the NDP. Finally, there are linkages between components and between components and objectives (e.g. absence of quality assurance system ➡ poor quality of drugs, withdrawing irrational drugs ➡ less irrational use of drugs, etc.). More in-depth analysis is however needed to identify reliable trends.

2.3 Preliminary findings based on the political mapping

The workshop participants discussed the main findings of the political mapping analysis, regarding both the process of the analysis and the substance of the analysis. The following preliminary ideas emerged in the discussion.

(a) The process of political mapping analysis

Participants agreed that the analysis in six countries demonstrated that it is possible to examine policy-making processes, using a systematic step-by-step, method, and that the analyses yielded important benefits to both policy-makers and policy analysts. This finding supports the proposal that policy-making is not simply a technical process, but also a political process, and that policy-makers need both technical and political analysis in order to be effective. The method of political mapping is one form of applied political analysis, which can assist the development and implementation of national drug policies.

(b) Policy-making is a continuous process

Policy-making does not stop with the official adoption of a policy (such as the Generics Law in the Philippines), but continues on through the phase of implementation. To assure the effective implementation of a policy requires continuous tending, caring, revising, and weeding, much like a garden. Lack of attention during the phase of implementation can result in a policy falling into disrepair or even reversal. In many ways, the most difficult challenges occur during implementation, when the goals and mechanisms of a policy must be put into practice.

(c) Interest groups are not often monolithic

Several country teams reported instances where the ability to split or unite key interest groups affected the success or failure of adopting a major change in national drug policy. For example, the unification of the domestic and international drug industry in India significantly enhanced the chances of the major changes in the drug laws in that country. In Thailand as well, the proposal of the government united the domestic and international industry, which contributed to the reversal of the policy on drug labelling. Whether the physicians are unified in a single interest group or divided into specialists versus general practitioners can also affect the feasibility of a policy change. Policy advocates need to be aware of these potential splits in interest groups, and the impact on the feasibility of policy change or policy implementation. Often, these splits can be avoided (or created) through effective political strategies and negotiations by policy-makers.

(d) Policy-making has controllable and uncontrollable events

Policy-making involves a complex series of strategic choices about the substance of a policy, about processes for introduction and adoption, and about organizations and mechanisms for implementation. Inevitably, these choices are affected by both controllable and uncontrollable events in the local, national, and international political environments. Policy-makers can improve the likelihood of success of their policies by seeking to identify the controllable events and to use them effectively, and be sensitive to the uncontrollable events and present their policy appropriately. Strategic concessions in the substance of a policy can sometimes improve the chances of success; and the resistance to compromise can help create a coalition of opponents. Sometimes, the appeal to higher authorities can result in failure, as occurred when Thailand's FDA sought the opinion of the Council of State regarding its drug labelling act. The method of political mapping can help policy-makers in identifying both the controllable and uncontrollable events, and can suggest strategies for managing both.

(e) Some common strategies may exist

Some common strategies may exist that can help promote national drug policies. Additional comparative analysis of the six cases of political mapping will be necessary to identify these strategies and assess their effectiveness. Nonetheless, these common strategies would remain as suggestions. It is unlikely that a simple recipe exists for managing the formulation and implementation of all national drug policies. The approaches need to be developed and refined within specific national political contexts, and adapted over time to fit evolving political

circumstances and the problems that emerge in transforming the policy into practice.

3. Cross national analysis: What can be learnt at this stage?

During the last session of the workshop the participants reviewed what could be learnt from the comparative nature of the research. They tried to achieve the following:

- discuss the extent to which the methodologies successfully accomplished this cross national comparison;
- identify and substantiate strengths and weaknesses of existing policy from cross national perspectives;
- propose explanations for cross national variations in performance; and
- identify specific policy innovations from cross national learning that can improve the implementation of pharmaceutical policies.

The conclusions presented below are preliminary and need further analysis.

3.1 Relevance of the methods for cross national comparison

The group reviewed the usefulness and relevance of the two methods for cross national comparison.

Cross national comparison: the NDP indicators

The *strengths* of the indicators for a cross national analysis include:

- A high percentage of the indicators is relevant and useful in low and middle income countries: 80-90% of the indicators have been adopted by all countries included in the research.
- The indicators can be applied in national contexts and measure trends when collected over time.
- Data can be obtained at relatively low cost, compared to the amount of resources - public and private - which are spent on drugs.
- The logical framework (ST/PR/OT) is helpful for the interpretation of findings.

These strengths, associated with the fact that the method provides standardized results, make it possible to identify common problems and solutions and to learn through the comparison of the findings. The structural, background and outcome indicators are more useful for international comparison; for the process indicators, targets should normally be set at national level. To facilitate comparison, the group tried to introduce a rating system for all types of indicators. The same kind of system was used for developing Annex 5. However, additional efforts are needed to find optimal ways to relate indicators results to the overall scores and to weigh indicators, as all have not the same importance.

The group reviewed also some of the *limitations* of the indicators for cross national comparison, which include:

- the indicators are less easy to apply in countries with poor infrastructure and lack of reliable data;

- it is sometimes difficult to draw causal conclusions as outcomes are often multifactoral; in addition, multiple changes can occur over a single time, which makes it difficult to draw strong conclusions about a single factor.

Cross national comparison: the political mapping

The *strengths* of political mapping for cross national comparison include:

- the development of systematic political analyses, which can be compared across countries, to help in assessing the effectiveness of different political strategies for the promotion of national drug policies;

- the in-depth analysis of the policy process, which helps in assessing the feasibility of adopting different policy innovations, and the problems of implementation for national drug policies.

3.2 Strengths and weaknesses of NDP from a cross national perspective

A number of the findings which were discussed within each country framework are also valid from a cross national perspective. These include that it is *easier to put structures in place than to ensure they function* properly; that *nearly everywhere availability and affordability are seen as the first objectives to achieve*. The participants also felt that *for certain components there is a universal agreement of their importance* and of the fact that they should be taken care of everywhere in a kind of standardized approach:

- selection of drugs;
- procurement by tender in INN;
- drug pricing policy: governments have a role to play in this area of drug affordability although modalities can be different in different countries;
- continuous education and training is also a universal requirement although it is in general the least tackled of all the components.

In contrast, it seemed difficult to have a standardized pattern for budget allocations and public distribution systems.

It was also acknowledged that although all components are equally important everywhere, *countries will develop different priorities* based on what they perceived as their main problems. This will very often depend on the history of the pharmaceutical sector and the political and socio-economic characteristics of the country.

Time did not allow a review of the strengths or weaknesses of each country nor an attempt to explain them taking as a comparative tool the experiences of the other countries. It was agreed that this should be included in the next phases of the research.

3.3 Tentative explanations for cross national variations

This review of the variations among countries was based on the results of the two methods in the various countries. Tentative explanations for these differences include:

- There is an *obvious positive link between the performance of NDP and the economic development,* although this does not apply for all the aspects of the policy.

- *A number of technical components when implemented adequately make a great difference in terms of output:* for instance a bad selection of drugs and an inefficient procurement system lead invariably to shortages of drugs; on the contrary, a good registration system has a positive impact on rational use of drugs (Sri Lanka), a local manufacturing industry seems to have a positive influence on prices of drugs as long as the country is big (India). It was agreed that this last aspect should be analysed more in detail and followed carefully in view of the GATT agreements which may reverse the picture. A well-thought drug financing system can influence prescribing patterns. However, in all cases, supervision and monitoring are necessary.

- Countries with *no local industry* (national or multinational) can implement the main aspects of NDP with *less problems* (Sri Lanka).

- *Compulsory use of an EDL* in the public sector is just a *first step in improving availability and affordability*. These objectives seem more difficult to achieve in countries where pharmaceutical market is mostly private and where there is no regulation of drug prices (the Philippines).

- The *geographical situation of countries is also an important factor in the difference in performance,* e.g.: to be an island is an advantage as it makes drug imports easier to control (Sri Lanka).

- A *few motivated people can make a difference* between success and failure mainly to get things started but to rely on only a few people is dangerous as it does not ensure sustainability (Zimbabwe).

3.4 Policy innovations which can improve implementation of NDP

Policy innovations identified by the participants were related to the technical components and to the policy process. Under *technical components,* it seemed for instance that the creation of a social security system led to improved outputs of the policy (Colombia), the presence of a reimbursement system seemed to improve rational use of drugs as did some legislative requirements (e.g. in

Sri Lanka, the antidiarrhoeal drugs are forbidden and therefore none of the children in the survey received them).

In terms of *policy process*, it seemed that improvements of the NDP through radical changes are more likely to happen when there were political windows of opportunity (e.g. new regimes: the Philippines), changes in the global political/economic environment (GATT, global economic liberalization: India), etc. When such opportunities present themselves, it is possible to implement quick, radical and widespread changes (Philippines). When such opportunities are not available, it could be better to use low profile, step by step strategies (Sri Lanka).

Successful implementation of the policy is also influenced by the *planning process*: strategies used for one stage of policy-making affect the probability of success of other stages e.g. strategies in the formulation stage affect the probability of implementation; therefore planning for implementation is important even at the time of the formulation of policy.

It was stated by the participants that an important lesson of the research at this stage was that the technical soundness and/or economic rationality of the policy did not always imply that the policy was politically viable.

Cross national approach

The comparative cross national approach pursued in the research was valuable as, even at this very preliminary stage of analysis, it was possible to better explain the particular aspects of each country's policy and to identify more universal aspects of policy-making. It also helps in selecting policy interventions which have worked in one country and can be replicated in others. Finally, the two methods which have been used in the project seemed to be useful not only within countries to assess and improve the pharmaceutical situation but also for cross national comparison and for theory building.

4. Broader capacity building

The research has also allowed an important process of capacity building. Although this process has not yet been quantified, all the country teams agreed that the research had a number of outputs:

(a) Pharmaceutical sector benefits

The results of the research have increased knowledge on key aspects of NDP and on successful strategies/policies. This provides an impetus for countries and for international agencies to reconsider their own policies in the pharmaceutical sector. In addition, the research will be useful in better targeting future research in the field of national drug policies, as it will assist in identifying the main issues which need to be addressed.

(b) Benefits for future research

Conducting the research strengthened skills and research capacity not only of the principal investigators but of a large number of people at national level who were involved in collection and analysis of data. It also enhanced the ability of the researchers to utilize better existing research as the project was an exercise where all the participants learnt and benefitted from research conducted in other countries. This experienced group of people should play a critical role in the future in their own countries.

(c) Political benefits

The research improved the information base at national and global level and provided evidence to influence policy-makers (Bulgaria, the Philippines) or to delay some decisions (Sri Lanka). At the same time, it revealed the lack of monitoring and the need to get good data for policy-making.

(d) Practical tools for policy analysis

The research project also demonstrated that the two research tools, the indicators and the political mapping, could be applied in diverse national contexts, for relatively low financial expenditures, and could generate useful information for policy-makers. The project indicated that these tools deserved broader adoption by policy-makers concerned with national drug policy.

V. Conclusions of the workshop and follow-up plans

1. Main outcomes

The workshop ended with considerable enthusiasm among all participants about the results achieved during the few days of the meeting; country teams and coordinators felt that the workshop had been a very important step in the research and was key for its continuation.

In summary, the workshop:

- provided one of the first occasions for countries to compare data collected in a standardized way. It showed the importance of having good methods and data and justified the WHO strategy of providing standardized methods for both national assessment and cross national comparison;

- permitted the review of the indicators and the political mapping as methods of policy analysis and assessments of NDP (field testing) and resulted in some improvements which will be incorporated in the next edition;

- allowed countries to share experiences in order to develop better approaches for policy formulation and implementation. Although there is no standard recipe for improving the policy process in countries, the workshop did come up with some useful conclusions;

- began the process of identifying specific strengths and weaknesses of existing policy from national and cross national perspectives; of generating hypotheses to explain how different pharmaceutical policies can affect the performance of the pharmaceutical sector; and of identifying specific policy innovations;

- showed the necessity to develop such research in countries with different socio-economic background; and to set up sustainable NDP monitoring systems in most countries;

- finally, enhanced the research capabilities of all the participants of the 12 countries.

2. Next steps

In order to finalize the research and to achieve the total expected outcomes, there are still a number of steps which need to be carried out in the months to come. These are:

- Improvement of the Excel programme DAP has prepared for processing and calculating the data for forwarding to the countries (July 1996).

- Finalization of the research at national level (data and reports), to be achieved by mid-September 1996.

- Comments from the three coordinating institutions on reports and data (end of October 1996).

- National workshops to disseminate the results and test hypotheses (end of February 1997).

- Writing of scientific articles and reports by the national teams for inclusion in a larger publication (end of April 1997).

- Organization of an international workshop in one of the countries involved (India has already proposed to host this). Its objectives will be: to review the hypotheses on policy process; to identify specific policy innovations from the cross-national approach that could improve the design and the implementation of pharmaceutical policy; and to propose ways to improve the political feasibility of implementing those innovations within specific political contexts.

- Preparation, editing, publishing and dissemination of the results through various publications.

Funding will be sought by DAP and IHCAR to carry out all these activities. If funding is not available, a contingency plan will be made at a later stage.

A number of countries have done the political mapping; for the time being, there are no funds to do this exercise in new countries but people are welcome to contact Michael Reich for advice by e-mail. It is also possible that students from Harvard or people from the region, who are already trained in the methodology, can assist countries in the political mapping.

Annex 1: Research proposal

COMPARATIVE ANALYSIS OF NATIONAL DRUG POLICIES

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KAROLINSKA-HARVARD-WHO PROJECT

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I. Introduction

This research protocol for the Karolinska-Harvard-WHO project on the comparative analysis of National Drug Policies (NDPs) in developing countries includes: brief description of the problem, the research question, and the study's objectives; the anticipated outcomes from the cross-national comparative study; a description of the principal analytic methods to be used; and the proposed work plan and project collaborators. The accompanying background paper (Govindaraj, 1994) presents a comprehensive review of the literature on the formulation, implementation, and evaluation of social programs; and provides the rationale and theoretical basis for the research protocol.

II. The Problem

Effective, safe, affordable, and good quality drugs are an essential element of comprehensive health care (WHO, 1988; Hamrell et al., 1985; Sterky, et al., 1988; London School, 1989; Reich, 1987; Kanji, et al., 1992). There is increasing recognition that serious problems exist in many current pharmaceutical systems, especially in Third World countries (see the Background Paper). The WHO has designed guidelines for the development of national drug policies (WHO, 1988) to include legislation/regulation, regulatory control, pricing, distribution, drug selection, drug prescribing, dispensing, quality assurance, and manpower aspects. The WHO guidelines are based on the concept of essential drugs - that a model list of about 250 drugs could serve about 90 per cent of the morbidity within a country (WHO, 1977). These guidelines, however, provide little information about the processes of policy development and implementation. In addition, the WHO is just beginning to develop methods to assess the performance of pharmaceutical policy.

In the past 20 years, numerous initiatives have been taken in formulating and implementing pharmaceutical policies in developing countries. During the 1980s, the leadership provided in this field by the Action Program on Essential Drugs (APED) at the World Health Organization was actively supported by bilateral aid agencies, nongovernmental organizations, industry associations, and university research groups. Furthermore, many bilateral and multilateral agencies also became involved in promoting and supporting pharmaceutical policy development. In the late 1980s, attention turned to issues of health financing and drugs (through UNICEF's Bamako Initiative) and to issues of drug utilization (illustrated by the International Network on the Rational Use of Drugs). In the 1990s, improving the pharmaceutical sector in developing countries was cited as a priority by the World Bank in its 1993 *World Development Report*.

Various groups have studied national drug policies (NDPs), based on the concept of essential drugs (Chowdhury, 1992; Goonaratne, 1989; Kanji, et al., 1989; Kanji, et al., 1992; Kiatying-Angsulee, et al., 1992; Reich, 1994; Tomson, 1990; WHO, 1992). The global policy analysis of the WHO Action Program on Essential Drugs (APED) in 1989 (London School, 1989) assessed these efforts at pharmaceutical policy development and emphasized the spread of Essential Drug Lists as an achievement and the limited

adoption of National Drug Policies as a problem. Others identified weaknesses in the Information-Education-Communication component together with a lack of focus on the rational use of drugs (Finer, et al., 1992). A third group stressed the supply orientation of many essential drug programs (Kanji, et al., 1989), and criticized the tendency for national drug policy to be reduced to a drug supply system. As pointed out in the Background Paper, however, there have been few systematic reviews and analyses of the national and international efforts at pharmaceutical policy development and their accomplishments.

The above reports suggest that while the WHO program has effectively identified key elements of a national drug policy and has disseminated information on these ideas, APED has encountered difficulties in promoting the national implementation of new policies and in articulating how the public and private sectors can positively interact in the pharmaceutical sector. In addition, the existing studies have suffered from two main problems: first, they have lacked systematic comparisons of in-depth national studies; and second, they have, therefore, been unable to provide innovative ideas for improving the formulation and implementation of national drug policies. This research project seeks to address both of these deficiencies.

III. Research Question and Objectives of Proposed Study

The overall goal of the project is to assess the performance of national pharmaceutical policies in developing countries (focusing on policy outputs *and* policy process), to analyze the reasons for their success or failure, and to propose strategies for improvement. The principal research question that the project seeks to answer is: Have National Drug Policies (whether they exist as explicit policy documents, or are implicit in government actions) in developing countries been successful in achieving the goals of availability, accessibility, good quality, and rational use of essential drugs? Why or why not?

The project will combine several disciplines (policy analysis, economics, and epidemiology/medicine/pharmacy) in order to assess national accomplishments, and develop fresh perspectives on national and international initiatives. Attention will be given, where warranted, to the interaction of public and private sectors in the pharmaceutical field of each country. Within this context, the specific objectives are:

a) To identify strengths, weaknesses, and political dimensions of pharmaceutical policy formulation and implementation within each country;

b) To propose explanations for cross-national variations in performance; and

c) To propose effective strategies, both national and international, that can improve pharmaceutical policy implementation.

IV. Study Approach

The project will have three phases: planning, research and dissemination. The research phase is described in this section; for details of the planning and dissemination phases, see Section 7 below.

The research phase will evaluate national drug policies in 8 developing countries, and will produce a series of country studies that examine key processes of policy formulation and implementation. The research will combine summative and formative evaluation strategies (see Background Paper). Both quantitative and qualitative measures and approaches (described below) will be used in carrying out the analysis.

The 8 countries selected for this project are: Colombia, Guinea, India, Philippines, Sri Lanka, Vietnam, Zambia, and Zimbabwe. These developing countries from Africa, Asia, and Latin America have been chosen based on the following criteria: socio-economic status, political system and regime type, geographical and demographic factors, colonial history, existence or absence of a formal NDP, public-private mix and size of domestic pharmaceutical industry, availability of in-country contacts, and the existence of previous studies. They include some of the world's poorest countries, as well as some middle-income countries; countries with no pharmaceutical manufacturing capacity, as well as some with substantial capacity.

The implementation of the research phase of the project will involve:

1: Assessment of NDP performance, through the application of a standard set of indicators, in order to evaluate NDP outcomes as well as processes.

2: Two rounds of group evaluation as a means for a) Achievement of group consensus on methodologies, and the training of the country team coordinators (Round 1), and b) a comparative analysis of strengths and weaknesses of NDPs, and identifying key questions for the political mapping (Round 2).

3: Analysis of the NDP formulation and implementation processes, through the application of political mapping, in order to assess organizational and political variables. A second round of political mapping may be undertaken in a subset of the study countries, aimed at addressing specific questions that emerge from the first round of evaluations and political mapping.

V. Anticipated Outcomes

1. The project will apply a systematic cross-national method for the assessment of pharmaceutical policy performance, using summative and formative evaluation techniques, through the standardized indicators and the political mapping technique.

2. The assessment of pharmaceutical policy performance will provide the basis for generating hypotheses to explain how different pharmaceutical policies, especially different public/private mixes, can affect the performance of the pharmaceutical sector.

3. The project will assist policy-makers responsible for pharmaceutical policy in identifying and substantiating specific strengths and weaknesses of existing policy, from national and cross-national perspectives, and in formulating strategies to improve the implementation of pharmaceutical policy.

4. The project will provide field testing of the standard indicators and the political mapping technique in a series of countries, and their potential development into a method of policy analysis and rapid assessment of pharmaceutical sector performance.

5. The project will facilitate the collection of data for the WHO's forthcoming *World Drug Situation Report*.

6. The project will identify specific policy innovations from cross-national learning that could improve the design and implementation of pharmaceutical policy within each country, and will propose ways to improve the political feasibility of implementing those innovations within a specific political context.

7. The project will enhance the capacity of Essential National Health Research within each country, through the development and application of the policy performance assessment methodology and the political mapping methodology, both of which can be applied to other areas of health policy.

8. The project will provide an impetus for international agencies to reconsider their own policies for the pharmaceutical sector, and will assist in strengthening the policy analysis capabilities of international agencies involved in supporting the development of national pharmaceutical policy.

VI. Methods

This project's evaluation of NDPs will use a comparative, cross-national analysis to place each country's experiences within a broader international context, and to explain both the particular features of a country's policy and more universal aspects of policy-making (Reich, 1988). Cross-national studies of health policy in developing countries are relatively few in number. In the late 1970s, Montgomery, Lasswell, and Migdal published a book on population policies, which used comparative and longitudinal approaches to

analyze patterns of policies (Montgomery, et al., 1979). Their study explicitly examined both the processes of policy making and implementation as well as the substance of population policy, and thereby represents a potential model for this project. A recent book on the policies and politics of AIDS in the industrialized countries represents another effort to use a comparative approach to health policy from both substantive and procedural perspectives (Kirp et al., 1992). There are a few publications of collected essays on pharmaceutical problems in developing countries (Robles, et al., 1992; Geest, et al., 1988). No studies, however, specifically focus on pharmaceutical policy, and the analyses of pharmaceutical policy that exist rarely explore the problems of policy performance and implementation in a systematic manner. This project, thus, will represent a significant advance in the empirical application of comparative policy analysis in developing countries.

The three methods of standardized indicators, group evaluation, and political mapping are described next.

1. Performance Indicators

Purpose of Indicators: The standardized indicators represent a tool for summative and formative evaluation (see Background Paper). The proposed indicators serve two primary purposes:

a) To evaluate the *outcomes* of pharmaceutical policies in a comparative framework; and

b) To assess pharmaceutical policy formulation and implementation (i.e. policy *process*).

The outcomes of the NDPs will be measured according to the four common goals of NDPs in developing countries: availability, accessibility, good quality and rational use of drugs. In addition, other country-specific goals may be added to the evaluation. The assessment of success will be based on the extent to which countries have been able to achieve the precise goals and targets (initial or evolving) that they set for themselves (summative evaluation). In addition, the evaluation will examine the processes of policy formulation and implementation, and the institutional and political contexts in which the policies were implemented (formative evaluation).

Selecting the Indicators: The indicators for this comparative evaluation are selected from the indicators developed in a recent manual for monitoring national drug policies in developing countries (Brudon-Jakobowicz, Rainhorn and Reich, 1994). The indicators are classified as general data indicators, structural indicators, process indicators, and outcome indicators.

These are supplemented by some new indicators (in the form of standardized questions) based on hypotheses from the Background Paper for assessing relevant aspects of NDP formulation and implementation. The draft indicator manual, which lists the indicators, their purpose, description, and the methods of data collection, is provided as Appendix 2. A summary description of the project's indicators is provided next.

Description of Indicators: The policy formulation and implementation indicators (standardized questions) are based on hypotheses generated in the Background Paper, and focus on the *process* of pharmaceutical policy formulation. These indicators will supplement the political mapping methodology in assessing the organizational and political factors that affect the successful formulation and implementation of pharmaceutical policy.

The policy performance indicators are derived from the manual developed by a collaboration between APED/WHO, the Harvard School of Public Health, and the Centre de Recherches and d'Etudes pour le Développement de la Santé (Paris) (Brudon-Jakobowicz, et al., 1994), which followed nine logical steps:

1. *Literature Review* to identify potential key issues and components of pharmaceutical policy in developing countries.

2. *Delphi Survey* to develop consensus on key issues and components of pharmaceutical policy in developing countries.

3. *Experts Consultation* to review general difficulties in indicator development and define criteria for selection of indicators.

4. *Working Group* to propose sets of indicators for monitoring implementation of drug policy in developing countries.

5. *Field Testing* of proposed indicators in six countries to assess the clarity, applicability, and usefulness of the indicators selected.

6. *Review of the first draft manual by experts within and outside WHO* to assess the methodologies used for indicator development and the categories of indicators.

7. *Working group* to propose a set of outcome indicators to measure the progress toward the overall objectives.

8. *Review of methodology* for indicator calculation by some epidemiologists and statisticians within and outside WHO to assess the relevance of the proposed methodologies and appropriateness of the sampling procedures.

9. *Finalization of the manual.*based on a review of all comments received and incorporation of appropriate revisions.

The four categories of indicators are briefly described:

Background information are intended to provide data on the demographic, health, economic, and pharmaceutical contexts in which drug policy is being implemented in a given country. These indicators are quantitative data, at a single point in time, and in most countries are readily available at the central level. Some of the information will be used in calculating subsequent indicators. Some data may be useful in cross-national comparisons of drug policy implementation.

Structural indicators provide qualitative information to assess the pharmaceutical system's capacity to achieve its policy objectives. These indicators are intended to check if the key structures necessary to implement a pharmaceutical policy are present in the country. Seven categories of key components are considered: legislation and regulation, essential drug selection and drug registration, drug allocation in the health budget/public sector financing policies, public sector procurement procedures, public sector distribution and logistics, pricing policy, information and continuous education on drug use. The indicators can be used in comparing the pharmaceutical policies of different countries and in assisting national and international decision-makers to design interventions to improve the pharmaceutical sector.

Process indicators provide quantitative measurements of the processes by which a national drug policy is implemented. The indicators assess the degree to which activities are being effectively implemented and the progress over time. The process indicator monitor the main aspects under the same seven key components of drug policy. These indicators can be used for assisting national decision-makers in monitoring progress in the implementation of the drug policy in relation to goals and targets set up at the national level.

Outcome indicators are intended to measure the results achieved and the changes that can be attributed to the implementation of a national drug policy. These indicators measure the effects of the policy on the overall objectives: availability and affordability of essential drugs, drug quality, and the rational use of drugs. These indicators can be used in assisting national and international decision-makers in measuring progress towards overall objectives and adjusting strategies accordingly, and in comparing pharmaceutical policies of different countries.

Implementation of Indicators: The application of these indicators will be carried out by the respective country teams. The methodology for calculating the indicator, including a detailed discussion of the procedures for conducting surveys, as well as potential sources for the required information, are provided in the indicator manual (Appendix 2).

2. Group Evaluation

Purpose of Group Evaluation: The group evaluation will be carried out in two rounds, with two main purposes:

a) To assist in the initiation of the field research by training the participants in the indicator and political mapping research methodologies, and to achieve group consensus on a common approach [Round 1].

b) To review the accomplishments and conclusions of the application of the indicators and the political mapping, in a comparative framework, and in a critical but supportive group process; and to identify specific questions of possible interest to all developing countries implementing NDPs, for further investigation [Round 2].

Description of Group Evaluation: Group evaluation will involve the following activities:

Round 1:

1) training the participants in the two research methods and achieving group consensus on the application;

2) comparing the available policy performance indicators for all countries;

Round 2:

3) discussing the performance methodologies and proposing adjustments, with particular consideration of its potential incorporation into national health policy information systems;

4) discussing cross-national comparisons, and the extent to which the methodologies successfully accomplished this objective;

5) examining proposed explanations for relative strengths and weaknesses of pharmaceutical policy performance in different countries;

6) identifying specific questions relevant to NDP implementation, which could be usefully investigated in some countries in a second round of political mapping; and

7) reviewing policy interventions that could improve pharmaceutical policy performance in each participating country.

Implementation of Group Evaluation: Round 1: The first round of group evaluation will occur after each country team has performed a preliminary analysis of the indicators, in preparation for the full application of the indicators and political mapping. This meeting is scheduled for October, 1994.

Round 2: The second round of group evaluation will occur after the full application of the indicators and the political mapping. Each country team will prepare an evaluation of pharmaceutical policy performance, including: 1) the results of the performance indicators and the political mapping exercise, 2) an evaluation of the performance methodology, and 3) a document that proposes explanations for strengths and weaknesses shown by the indicators and the political mapping. These three sets of materials will be

critically reviewed by the participants from the three collaborating institutions, and representatives from the country teams. Questions to be investigated in certain countries will also be identified.

3. Political Mapping

Purpose of Mapping: Political mapping has three main goals for this project:

a) To assess the organizational and political determinants of the policy process;

b) To help explain the strengths and weaknesses identified by the performance indicators; and

c) To assist in the identifying and assessing strategies to improve pharmaceutical policy implementation.

Description of the political mapping process: Political mapping constitutes the third method of the research, and provides an analysis of the process of NDP formulation and implementation. The overall objective of political mapping is to assist decision-makers in improving the implementation of health policies.

This methodology has descriptive, explanatory, and prescriptive objectives: to describe the consequences, stakeholders, interests, and networks involved in a particular policy; to help explain how and why a particular decision was reached in the past; and to assist decision-makers in managing the politics of formulation or implementation (Reich, 1993).

Political mapping involves six discrete steps, presented in detail in the mapping manual (Appendix 3):

Step One: *Policy Consequences*: describes the policy's consequences along four dimensions: the size, identity, intensity, and timing of the effects.

Step Two: *Position Map*: provides a map of the proponents and opponents of the health policy, according to international sector, political sector, government sector, private sector, nongovernmental sector, and social sector.

Step Three: *Stakeholder Analysis*: determines the main interests and objectives of each organization, and the organizational priority of the interests.

Step Four: . *Policy Network Analysis*: identifies the formal and informal linkages between organizations and individuals.

Step Five: *Transitions Assessment*: identifies major transitions underway in the organization responsible for implementing the policy, the general organizational environment, and the broader political environment.

Step Six: *Strategies for Change*: analyzes potential strategies for changing or influencing policy-making processes and outcomes according to symbolic, positive, and negative strategies.

This methodology is currently under development at the Harvard School of Public Health. It has been applied to a series of health policy problems, and has been shown to provide rapid identification of problems, to improve communication among organizations, and to assist policy-makers in identifying effective new strategies for policy implementation.

Implementation of Political Mapping: The political mapping will be undertaken by each country team, assisted by the three collaborating institutions. The mapping will be based on published documents as well as non-published documents (including internal government memoranda) and interviews with key policy-makers in the stakeholder organizations in both public and private sectors. The mapping process, thus, will require active interaction with policy-makers responsible for pharmaceutical policy. It is expected that the results of the political mapping will be helpful to policy-makers in designing effective strategies to improve implementation. Detailed guidelines on implementing the mapping exercise are provided in Appendix 3.

A second round may be instituted in some countries, in order to pursue questions identified by the group evaluation as particularly germane to NDP formulation or implementation in developing countries.

VII. Time Line and Resources

Project Work Plan

The project will have three phases: Planning, Research and Dissemination.

The *planning phase* will review the conceptual framework and finalize participating researchers, including senior people in the international health field who could serve as advisors of the project. To assure adequate consideration of private sector issues, advisors will also be sought, toward the end of the research phase, from major pharmaceutical companies in the United States, Europe, and Japan. A planning session of about 6 to 8 people was held at the Karolinska Institute in March 1994, to review research outlines and analytic approaches.

The *research phase*, as mentioned, will produce a series of country studies plus analytic essays that compare the performance of national pharmaceutical policies and examine policy-making processes at the national and international levels. Particular attention will

be given to the mixture of public and private sectors and ways to resolve tensions between public and private interests.

The *dissemination phase* will begin with an international meeting, including representatives of the major organizations involved in pharmaceutical policy, with the objective of debating the project's research results. Efforts will be made to disseminate the conclusions to national policy-makers as well as decision-makers in international agencies.

Project Collaborators

The three main collaborators in the project are: the Department of International Health Care Research (IHCAR), Karolinska Institute; the Department of Population and International Health and Takemi Program in International Health, Harvard School of Public Health; and the Action Program on Essential Drugs, WHO. The project will be coordinated by Dr. Göran Tomson, MD, PhD, of Department of International Health Care Research (IHCAR) at the Karolinska Institute, assisted by Dr. Kris Weerasuriya, MD, PhD, Senior Lecturer, Department of Pharmacology, University of Colombo, Sri Lanka; Professor Michael R. Reich, PhD, of the Department of Population and International Health, also Director of the Takemi Program in International Health at Harvard School of Public Health, assisted by Dr. Ramesh Govindaraj, MD, MS, Doctoral Candidate, Harvard School of Public Health; and Mrs Pascale Brudon-Jakobowicz, Scientist, APED, WHO. The coordinators represent the fields of health systems research, political science, health economics, and pharmacology.

Each coordinating institution is responsible for providing support in two or three of the eight selected countries: Sri Lanka, Vietnam, and Zambia will be supported by the Karolinska Institute; Colombia and India, by the Harvard School of Public Health; and Guinea, the Philippines, and Zimbabwe by the WHO. The collaborating institutions will be responsible for providing technical support and backstopping in the selected countries.

Each country research team should ideally include: an epidemiologist/statistician, an economist/social scientist, and a policy analyst, and possibly a computer analyst. However, it can be difficult in some countries to find such individuals; in this case the country coordinator will select the best available researchers. Each country's research team will be headed by a coordinator, who will have the overall responsibility for carrying out the field research in that country. The country coordinator will also be responsible for choosing the other members of the research team, and determining their individual responsibilities. The coordinator should have a good knowledge of the pharmaceutical sector in his/her country, and should possess the necessary disciplinary background, managerial and inter-personal skills, and adequate time to undertake project responsibilities.

The project will begin in Fall, 1993, for a two-year period, with a planning session in March, 1994, and a major international meeting to disseminate findings at the end of 1995. The project schedule is presented below.

Project Schedule

Fall, 1993	- Preparatory meeting among project coordinators, at the Harvard School of Public Health
March, 1994	- Planning session in Stockholm to review the conceptual framework and select the participating countries
June, 1994	- Indicators to be finalized by mid-June. Four background documents (background paper, project protocol, indicator manual and mapping manual) to be completed by mid-June. Country coordinators to be identified by the end of June.
July, 1994	- An official letter of invitation to join the project to be sent to each country team, along with copies of background documents, etc. by end of July.
Oct., 1994	- Round 1 of Group Evaluation: Planning session of country coordinators and international coordinators in Geneva, to review research methods and initiate research project.
Nov., 1994-Feb., 1995	- Data collection and analysis of Indicator surveys to be undertaken between October, 1994 - Feb., 1995. A country visit by a member of the coordinating institution will be undertaken in Jan-Feb., 1995.
March-June, 1995	- Political mapping of the process of NDP formulation and implementation to be carried out in participating countries
July, 1995	- Round 2 of Group Evaluation: International meeting of research team representatives in a developing country to discuss research findings and policy implications and prepare for next round of mapping
July, 1995 - Nov., 1995	- Second round of political mapping in selected countries, focusing on specific questions
Dec., 1995	- Major international meeting to discuss full research findings, and disseminate the results

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Annex 3: Agenda

Second workshop on the research on the comparative analysis of NDP

Action Programme on Essential Drugs
World Health Organization
Room M-505

Day 1, Monday, 10 June 1996

Session I: Introduction

09:00-10:00	Introductory remarks by Dr Fernando S. Antezana, ADG
	Opening of the workshop by Dr Jonathan D. Quick, Director, DAP
	Introduction of participants
	Introduction to the workshop by Mrs Pascale Brudon, DAP

Session II: NDP Performance assessment (indicators)

10:00-16:00	Presentation by countries (15 minutes each)
	Presentation by countries (15 minutes each)
16:00-17:30	Identification and discussion of key methodological problems

Day 2, Tuesday, 11 June 1996

09:00-11:00	Discussion and resolution of key methodological problems
11:00-16:30	Analysis and interpretation of the findings
16:30-17:30	Synthesis of Session II

Day 3, Wednesday, 12 June 1996

Session III: Political mapping

09:00-12:00 Presentation by countries

14:00-16:00 Discussion on similarities and differences

16:00-17:00 Plenary and synthesis of Day 3

Day 4, Thursday, 13 June 1996

Session IV:

09:00-12:30 Cross national comparison:

- relevance of the systematic cross national method which has been used in the research for assessing NDP;
- review of the hypothesis developed to explain how different strategies affect the outcomes of the policy;
- review of the explanations developed for cross national variations in NDP performance.
- formulation of national and international strategies and specific policy innovations to improve implementation of national drug policies.

14:00-16:00 Planning next steps

- time schedule for the preparation of the final reports, including methodological refinements;
- strategies for dissemination of the results, including national and international seminars and publications;
- collaboration with policy-makers and donor organizations;
- funding issues. etc.

16:00 Closing remarks

Annex 4: Questionnaire on NDP performance assessment

Second workshop on the research on the comparative analysis of NDP

1. The relevance of the method to assess your country's policy

1. Were you able through the use of the indicators to evaluate the outcomes of your NDP?

2. Were you able through the use of the indicators to assess the implementation of the NDP?

3. Did you find things you did not know about the NDP from the indicators?

4. Which aspects of the NDP were not covered by the indicators?

2. The findings:

Based on the data collected (ST, PR, OT indicators), there are at least four questions:

Please circle the correct number.
1 = does not work
5 = works very well

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	3	4	5
• accessibility to essential drugs?	1	2	3	4	5
• quality of drugs?	1	2	3	4	5
• rational use of drugs?	1	2	3	4	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

Please circle the correct number.
1 = does not work
5 = works very well

(a)	Legislation and regulation	1	2	3	4	5
(b)	Essential drugs selection and drug registration	1	2	3	4	5
(c)	Drug allocation in the health budget/public sector financing policy	1	2	3	4	5
(d)	Public sector procurement procedures	1	2	3	4	5
(e)	Public sector distribution and logistics	1	2	3	4	5
(f)	Pricing policy	1	2	3	4	5
(g)	Information and continuing education on drug use	1	2	3	4	5

Comments, if needed:

_____

_____

_____

_____

_____

3. What is your assessment of the strengths of the national drug policy?

_____

_____

4. **What is your assessment of the weaknesses of the national drug policy?**

3. The analysis and interpretations of the findings

		Yes	*No*
1.	Are there components (a, b, c, d, e, ...) which have received more attention and were implemented first? If yes, can you identify the reasons for this?	❑	❑
2.	Were there components (a, b, c, d, e, ...) that were easy to implement and components that were difficult to implement? If yes, can you identify which ones and why?	❑	❑

3. Are there components (a, b, c, d, e, ...) which seem to have been more important for achieving the NDP objectives than others? If yes, can you explain why? ❑ ❑

4. Were there any linkages in performance across components, so that if one component was performing well, other also performed well? If yes, can you comment upon? ❑ ❑

Annex 5: Achievements of the national drug policies in the 12 countries

This annex contains a one-page table for each country which used the NDP indicators for assessing its national drug policy, namely Bulgaria, Chad, Colombia, Guinea, India, Mali, Philippines, Sri Lanka, Thailand, Viet Nam, Zambia and Zimbabwe.

Each page contains rated information on:

1. The achievement of the NDP in relation to the four objectives: availability of essential drugs, accessibility of essential drugs, quality of drugs, rational use of drugs.

2. The level of implementation of each key component of the NDP: legislation and regulation, essential drugs selection and drug registration, drug allocation in the health budget/public sector financing policy, public sector procurement procedures, public sector distribution and logistics, pricing policy, information and continuing education on drug use (structure and process).

The rating was done by the teams during the workshop on the basis of the data collected in each country. It used both calculation of averages and judgment related to the relative importance of the various indicators in each subgroup. It was refined later in DAP once new and more accurate data were sent by the countries (see Annex 6).

It should however be seen as tentative and is provided in this annex as an example of what can be achieved with the results of an indicator exercise.

Achievement of NDP

BULGARIA

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	3	**4**	5
• accessibility to essential drugs?	1	**2**	3	4	5
• quality of drugs?	1	2	**3**	4	5
• rational use of drugs?	1	2	**3**	4	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	2	3	**4**	5
	Process	1	**2**	3	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	**3**	4	5
	Process	1	2	**3**	4	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	**2**	3	4	5
	Process	1	**2**	3	4	5
d. Public sector procurement procedures	*Structure*	1	2	3	4	**5**
	Process	1	2	3	**4**	5
e. Public sector distribution and logistics	*Structure*	1	2	3	**4**	5
	Process	1	2	3	**4**	5
f. Pricing policy	*Structure*	1	2	**3**	4	5
	Process	1	2	**3**	4	5
g. Information and continuing education on drug use	*Structure*	1	2	**3**	4	5
	Process	1	**2**	3	4	5

The correct number is circled.
1 = does not work
5 = works very well

Achievement of NDP

CHAD

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	❸	4	5
• accessibility to essential drugs?	1	2	❸	4	5
• quality of drugs?	❶	2	3	4	5
• rational use of drugs?	1	2	❸	4	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	❷	3	4	5
	Process	❶	2	3	4	5
b. Essential drugs selection and drug registration	*Structure*	1	❷	3	4	5
	Process	1	❷	3	4	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	2	❸	4	5
	Process	1	2	3	4	5
d. Public sector procurement procedures	*Structure*	1	❷	3	4	5
	Process	1	2	3	4	5
e. Public sector distribution and logistics	*Structure*	1	❷	3	4	5
	Process	1	2	❸	4	5
f. Pricing policy	*Structure*	1	❷	3	4	5
	Process	1	❷	3	4	5
g. Information and continuing education on drug use	*Structure*	❶	2	3	4	5
	Process	1	❷	3	4	5

The correct number is circled.
1 = does not work
5 = works very well

Achievement of NDP

COLOMBIA

1. **Has the policy achieved the objectives of:**

• availability of essential drugs?	1	2	3	**4**	5
• accessibility to essential drugs?	1	2	3	**4**	5
• quality of drugs?	1	2	3	**4**	5
• rational use of drugs?	1	2	**3**	4	5

2. **Which components of the policy work and which ones do not work (policy structures and processes)?**

a. Legislation and regulation	*Structure*	1	2	3	**4**	5
	Process	**1**	2	3	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	3	**4**	5
	Process	1	2	3	**4**	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	2	3	**4**	5
	Process	1	2	**3**	4	5
d. Public sector procurement procedures	*Structure*	1	2	3	4	**5**
	Process	1	2	**3**	4	5
e. Public sector distribution and logistics	*Structure*	1	2	3	**4**	5
	Process	1	2	3	**4**	5
f. Pricing policy	*Structure*	1	2	3	**4**	5
	Process	1	2	**3**	4	5
g. Information and continuing education on drug use	*Structure*	1	**2**	3	4	5
	Process	1	**2**	3	4	5

The correct number is circled.
1 = does not work
5 = works very well

Achievement of NDP

GUINEA

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	3	**4**	5
• accessibility to essential drugs?	1	**2***	3	**4**	5
• quality of drugs?	1	**2**	3	4	5
• rational use of drugs?	1	2	**3**	4	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	2	3	**4**	5
	Process	**1**	2	3	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	3	**4**	5
	Process	1	2	**3**	4	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	**2**	3	4	5
	Process	1	**2**	3	4	5
d. Public sector procurement procedures	*Structure*	1	2	**3**	4	5
	Process	1	2	**3**	4	5
e. Public sector distribution and logistics	*Structure*	1	2	3	**4**	5
	Process	1	2	3	**4**	5
f. Pricing policy	*Structure*	1	**2**	3	4	5
	Process	1	2	**3**	4	5
g. Information and continuing education on drug use	*Structure*	**1**	2	3	4	5
	Process	**1**	2	3	4	5

The correct number is circled.
1 = does not work
5 = works very well
* for the private sector

Achievement of NDP

INDIA

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	**3**	4	5
• accessibility to essential drugs?	1	**2**	3	4	5
• quality of drugs?	1	**2**	3	4	5
• rational use of drugs?	**1**	2	3	4	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	2	3	**4**	5
	Process	**1**	2	3	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	3	**4**	5
	Process	1	2	**3**	4	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	**2**	3	**4**	5
	Process	1	**2**	3	4	5
d. Public sector procurement procedures	*Structure*	1	2	**3**	4	5
	Process	1	2	**3**	4	5
e. Public sector distribution and logistics	*Structure*	1	2	3	**4**	5
	Process	1	2	3	4	5
f. Pricing policy	*Structure*	1	**2**	3	4	5
	Process	1	2	**3**	4	5
g. Information and continuing education on drug use	*Structure*	**1**	2	3	4	5
	Process	**1**	2	3	4	5

The correct number is circled.
1 = does not work
5 = works very well

Achievement of NDP

MALI

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	**3**	4	5
• accessibility to essential drugs?	1	2	3	4	5
• quality of drugs?	1	2	3	4	5
• rational use of drugs?	1	**2**	3	4	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	2	3	**4**	5
	Process	1	**2**	3	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	3	**4**	5
	Process	1	**2**	3	4	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	**2**	3	4	5
	Process	1	**2**	3	4	5
d. Public sector procurement procedures	*Structure*	1	2	3	**4**	5
	Process	1	**2**	3	4	5
e. Public sector distribution and logistics	*Structure*	1	2	**3**	4	5
	Process	1	**2**	3	4	5
f. Pricing policy	*Structure*	1	2	**3**	4	5
	Process	1	2	**3**	4	5
g. Information and continuing education on drug use	*Structure*	1	**2**	3	4	5
	Process	**1**	2	3	4	5

The correct number is circled.
1 = does not work
5 = works very well

Achievement of NDP

PHILIPPINES

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	**3**	4	5
• accessibility to essential drugs?	1	2	**3**	4	5
• quality of drugs?	1	2	3	**4**	5
• rational use of drugs?	1	2	3	**4**	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	2	3	**4**	5
	Process	1	2	**3**	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	3	**4**	5
	Process	1	2	3	**4**	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	**2**	3	4	5
	Process	1	2	3	4	5
d. Public sector procurement procedures	*Structure*	1	2	**3**	4	5
	Process	1	2	3	4	5
e. Public sector distribution and logistics	*Structure*	1	2	3	**4**	5
	Process	1	**2**	3	4	5
f. Pricing policy	*Structure*	1	2	**3**	4	5
	Process	1	2	3	4	5
g. Information and continuing education on drug use	*Structure*	1	2	3	**4**	5
	Process	1	2	**3**	4	5

The correct number is circled.
1 = does not work
5 = works very well

Achievement of NDP

SRI LANKA

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	3	4	**5**
• accessibility to essential drugs?	1	2	3	**4**	5
• quality of drugs?	1	2	**3**	4	5
• rational use of drugs?	1	2	**3**	4	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	2	**3**	4	5
	Process	1	2	**3**	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	3	**4**	5
	Process	1	2	**3**	4	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	2	3	**4**	5
	Process	1	2	3	**4**	5
d. Public sector procurement procedures	*Structure*	1	2	3	**4**	5
	Process	1	2	3	4	5
e. Public sector distribution and logistics	*Structure*	1	**2**	3	4	5
	Process	1	2	3	4	5
f. Pricing policy	*Structure*	1	2	**3**	4	5
	Process	1	2	3	4	5
g. Information and continuing education on drug use	*Structure*	1	2	**3**	4	5
	Process	1	**2**	3	4	5

The correct number is circled.
1 = does not work
5 = works very well

Achievement of NDP

THAILAND

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	3	4	5
• accessibility to essential drugs?	1	2	3	4	5
• quality of drugs?	1	**2**	3	4	5
• rational use of drugs?	**1***	2	3	4	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	2	3	**4**	5
	Process	1	2	**3**	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	3	**4**	5
	Process	1	**2**	3	4	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	2	3	4	**5**
	Process	1	2	3	4	5
d. Public sector procurement procedures	*Structure*	1	2	**3**	4	5
	Process	1	2	3	4	5
e. Public sector distribution and logistics	*Structure*	1	2	**3**	4	5
	Process	1	2	3		5
f. Pricing policy	*Structure*	**1**	2	3	4	5
	Process	1	2	3	4	5
g. Information and continuing education on drug use	*Structure*	1	2	3	4	**5**
	Process	1	2	3	4	5

The correct number is circled.
1 = does not work
5 = works very well
* mainly based on data from private drugstores

Achievement of NDP

VIET NAM

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	3	**4**	5
• accessibility to essential drugs?	1	2	**3**	4	5
• quality of drugs?	1	**2**	3	4	5
• rational use of drugs?	1	**2**	3	4	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	2	**3**	4	5
	Process	1	2	**3**	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	**3**	4	5
	Process	1	**2**	3	4	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	2	**3**	4	5
	Process	1	2	**3**	4	5
d. Public sector procurement procedures	*Structure*	1	**2**	3	4	5
	Process	1	2	3	4	5
e. Public sector distribution and logistics	*Structure*	1	2	**3**	4	5
	Process	1	2	3	**4**	5
f. Pricing policy	*Structure*	**1**	2	3	4	5
	Process	1	2	**3**	4	5
g. Information and continuing education on drug use	*Structure*	1	2	3	**4**	5
	Process	1	2	**3**	4	5

The correct number is circled.
1= does not work
5 = works very well

Achievement of NDP

ZAMBIA

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	❷	3	4	5
• accessibility to essential drugs?	1	2	3	4	5
• quality of drugs?	1	2	3	4	5
• rational use of drugs?	1	❷	3	4	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	2	❸	4	5
	Process	1	2	3	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	❸	4	5
	Process	1	2	3	4	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	❶	2	3	4	5
	Process	1	2	3	4	5
d. Public sector procurement procedures	*Structure*	1	2	❸	4	5
	Process	1	2	3	4	5
e. Public sector distribution and logistics	*Structure*	1	2	❸	4	5
	Process	1	2	❸	4	5
f. Pricing policy	*Structure*	❶	2	3	4	5
	Process	1	2	3	4	5
g. Information and continuing education on drug use	*Structure*	1	❷	3	4	5
	Process	1	2	3	4	5

The correct number is circled.
1 = does not work
5 = works very well

Achievement of NDP

ZIMBABWE

1. Has the policy achieved the objectives of:

• availability of essential drugs?	1	2	3	**4**	5
• accessibility to essential drugs?	1	2	3	**4**	5
• quality of drugs?	1	2	**3**	4	5
• rational use of drugs?	1	2	3	**4**	5

2. Which components of the policy work and which ones do not work (policy structures and processes)?

a. Legislation and regulation	*Structure*	1	2	3	**4**	5
	Process	1	**2**	3	4	5
b. Essential drugs selection and drug registration	*Structure*	1	2	3	4	**5**
	Process	1	2	3	**4**	5
c. Drug allocation in the health budget/public sector financing policy	*Structure*	1	2	**3**	4	5
	Process	1	2	3	**4**	5
d. Public sector procurement procedures	*Structure*	1	2	**3**	4	5
	Process	1	2	3	**4**	5
e. Public sector distribution and logistics	*Structure*	1	2	3	**4**	5
	Process	1	2	**3**	4	5
f. Pricing policy	*Structure*	1	**2**	3	4	5
	Process	1	2	3	**4**	5
g. Information and continuing education on drug use	*Structure*	1	**2**	3	4	5
	Process	1	2	**3**	4	5

The correct number is circled.
1 = does not work
5 = works very well

Annex 6: Consolidated tables

This annex contains the results of the indicators exercise in the 12 countries which participated in the workshop. These results are presented following the list of indicators and in two sets: the first one from page 85 to 99 covers Bulgaria, Chad, Colombia, Guinea, India and Mali; the second one from page 100 to page 114 covers the Philippines, Sri Lanka, Thailand, Viet Nam, Zambia and Zimbabwe.

Most of these data were presented during the workshop. They were then scrutizined for relevance, consistency, and reliability by Mrs K. Timmermans and Mrs P. Brudon, who received answers to their queries from the principal investigators of each country. The new consolidated tables were sent again to the country teams which reviewed them and finally a double check took place in Geneva using the consolidated table and the report for each country. However, it should be noted that some of these results are preliminary (Chad and Zambia). Some are incomplete (Sri Lanka); some are difficult to present in a table as they are structured differently (Colombia). Finally, in a number of cases, data alone do not provide a sufficiently clear picture, and there is a need to revert to country reports which will be available at a later stage.

The data were collected mainly at the end of 1995 and beginning of 1996. For data related to background information (BG1 to BG31), most of them refer to 1994.

NATIONAL DRUG POLICY - BACKGROUND INFORMATION

na = not available nr = not relevant

1. COUNTRY INFORMATION:	Bulgaria 1994	Chad	Colombia 1995	Guinea	India* Andhra Pradesh	Mali
Population data						
BG1: Total population (in millions)	8.4	6.6	37.5	6.3	70.5	8.8
BG2: Average annual growth of the population (%)	-0.38	2.4	2.2	2.8	2.4	3.5
BG3: Percentage of population living in urban areas (%)	67.8	21	73.8	30	36.7[1]	24
BG4: Life expectancy (years)	70.9	50.3	69	47	67.1 F/U[2] 60.7 F/R[2] 61.5 M/U[2] 57.3 M/R[2]	62 F[2] 59 M[2]
Economic data						
BG5: GNP per capita (USD)	1186[3]	169	1260	450	61	168
BG6: Average annual rate of inflation (%)	121.9[4]	(na)	23	4	13	25
2. HEALTH INFORMATION:	**Bulgaria**	**Chad**	**Colombia**	**Guinea**	**India Andhra Pradesh**	**Mali**
Health status data						
BG7: Infant mortality rate (per 1,000)	16.3	145	27.3	136	60	103
BG8: Maternal mortality rate (per 100,000)	20	800	64	623	259	1000

* NB: Figures for one state (Andhra Pradesh) only, unless when indicated that the answer applies to India

1 1991 census

2 F = female, M = male, U = urban, R = rural

3 Official statistical data

4 In a country with huge fluctuations like Bulgaria, trends are more important than annual figure

NATIONAL DRUG POLICY - BACKGROUND INFORMATION

	Bulgaria	Chad	Colombia	Guinea	India Andhra Pradesh	Mali
Health system data						
BG13: Total number of prescribers	40,390[1]	1,487	33,000	2,604	33,835	3,102
BG14: Total public health budget (million USD)	392	6.6	721	10.91	136.0[3]	6.5
BG15: Total value of international aid for the health sector (million USD)	2.68	42.2	26	(na)	(na) (187.4 India)	12[5] (1991)
BG16: Total health expenditure (million USD)	431	46.4[2]	1,604	(na)	(na)	103[5] (1991)
3. DRUG SECTOR INFORMATION:	**Bulgaria**	**Chad**	**Colombia**	**Guinea**	**India Andhra Pradesh**	**Mali**
Economic data						
BG17: Total public drug expenditure (million USD)	69.23	0.3	200	1.72 (1994)	9.26[3]	1.22
BG18: Total value of international aid for drugs (cash + kind) (million USD)	0.20	5.2	(nr)	(na)	0.02[3]	4.8
BG19: Total drug expenditure (public + households + international aid) (million USD)	105	8.3	1000	16.90 (1994)	83.25[4]	34.2
BG20: Total value of local production (ex-factory price) sold in the country (million USD)	66.6	0.2	980	0	657.1	4.9
BG21: Total value of drug imports (CIF) (million USD)	29.44	11.6	20	(na)	(na) (285.2 India)	11.7

1 Beside physicians (28,094), dentists and physician assistants are entitled to prescribe

2 Household expenditures are not included (not known); public health expenditures < budget.

3 Data from financial year '93/'94.

4 Data from 1992.

5 Figure from before the devaluation of the Franc CFA.

NATIONAL DRUG POLICY - BACKGROUND INFORMATION

	Bulgaria	Chad	Colombia	Guinea	India Andhra Pradesh	Mali
BG22: Total value of drugs under generic name (CIF and ex-factory prices) sold in the country (million USD)	(na)	6	250	1.7[3] (1994)	(na)	3.3 (1994)
Human resources						
BG23: Total number of pharmacists	4,500	31	5,000	401	1,746	313
BG24: Total number of pharmacy technicians or other aides/assistants	4,000	(na)	1,000	769	20,076	1,500
Drug sector organization						
BG25: Total number of drug manufacturing units in the country	64[1]	1	300	0	977	1
BG26: Total number of wholesalers in the country	480	2	90	7	7,827	5
BG27: Total number of pharmacies and drug outlets in the public sector (including health facilities and hospitals that dispense drugs)	1,180	(na)	3,250	399	1,817	77
BG28: Total number of pharmacies and drug outlets in the private sector	2,200	172	13,000	199	14,703	468
BG29: Total number of private pharmacies and drug outlets in the three major urban areas	1,002	103	5,400	116	1,844	139
Number of drugs						
BG30: Total number of registered drugs (in dosage forms and strengths)	5,000	(nr)[2]	14,000 (6,500 actually in the market)	1,446	(na) (60-80,000 India)	2,000
BG31: Total number of drugs on the national essential drugs list (in dosage forms and strengths)	(nr)	(240 INN)	435	207 (165 INN)	235[4]	313 (223 INN)

[1] Important drug manufacturers are only 12 to 14.

[2] Formal registration procedures not yet in place; 1,231 drugs are registred at Pharmat (largest supplier for the private sector)

[3] Estimation; data from NGOs, bi- and multilateral cooperation are not included.

[4] Figure concerns EDL for tertiary level; primary and secondary level have separate, shorter essential drugs lists.

NATIONAL DRUG POLICY - STRUCTURAL INDICATORS

	Bulgaria 1995	Chad	Colombia '95/'96	Guinea	India Andhra Pradesh	Mali
Legislation and regulation						
ST1: Is there an official national drug policy document updated in the past ten years?	N[1]	N	N	Y	Y	N
ST2: Is there drug legislation updated in the past ten years?	Y	N	Y	Y	Y	Y
ST3: Have regulations based on the drug legislation been issued?	Y	Y	Y	Y	Y	Y
ST4: Is there a drug regulatory authority whose mandate includes registration and inspection?	Y	Y	Y	Y	Y	Y
ST5: Is there a licensing system to regulate the sale of drugs (wholesalers, pharmacists, retailers)?	Y	Y	Y	Y	Y	Y
ST6: Are pharmacists legally entitled to substitute generic drugs for brand name products?	Y	N	Y	Y	N	N
ST7: Are there legal provisions for penal sanctions?	Y	Y	Y	Y	Y	Y
ST8: Is there a check-list for carrying out inspections in different types of pharmaceutical establishments?	Y	N	N	Y	N	Y
ST9: Are there any institutions within or outside the country where quality control is carried out?	Y	N	Y	N	Y	Y
ST10: Is the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce used systematically?	Y	N	Y	N	Y	Y
ST11: Are there controls on drug promotion based on regulations and consistent with the WHO ethical criteria for medicinal drug promotion?	Y	N	Y	N	Y	N

[1] Drug policy issues briefly discussed in the official national health policy document.

NATIONAL DRUG POLICY - STRUCTURAL INDICATORS

	Bulgaria	Chad	Colombia	Guinea	India Andhra Pradesh	Mali
Essential drug selection and drug registration						
ST12: Is there a national essential drugs list (EDL)/formulary using INN officially adopted and distributed countrywide?	N	N[2]	Y	Y	N	Y
ST13: Is there an official drug committee whose duties include updating the national essential drugs list (EDL)?	(nr)	Y	Y	Y	Y (N India)[4]	N
ST14: Has the national essential drugs list (EDL)/formulary been updated and distributed countrywide in the past five years?	(nr)	N[2]	Y	Y	Y (N India)[4]	Y
ST15: Do drug donations comply with the national essential drugs list (EDL)?	N[1]	N	(nr)	N	Y	N
ST16: Are there formal procedures for registering drugs?	Y	N	Y	Y	Y	Y
ST17: Is there a drug registration committee?	Y	Y[3]	Y	Y	N	Y
ST18: Is drug registration renewal required at least every five years?	Y	Y[3]	N	Y	N	Y
Drug allocation in the health budget/public sector financing policy						
ST19: Is the public drug budget spent per year more than 20% of the MOH operating budget spent per year for the last three years?	N	Y	(nr)	N	N	N
ST20: Is the public drug expenditure per capita more than US$1.00 per year for the last three years?	Y	N	Y	N	N	N

1 There is no national EDL; but a list of drugs needed which is not followed by donors.
2 EDL 1994 adopted but not distributed countrywide; EDL revision 1995 has been adopted, but is not yet distributed largely.
3 Legal provisions exist, but are not yet operational.
4 India does not have a national EDL, but A.P. State has.

NATIONAL DRUG POLICY - STRUCTURAL INDICATORS

	Bulgaria	Chad	Colombia	Guinea	India Andhra Pradesh	Mali
ST21: Is the public drug budget spent for national hospitals less than 40% of the total public drug budget spent for the last three years?	Y	(na)	(nr)	Y	N	N
ST22: Has the public drug budget spent per capita increased in the last three years?	N	(na)	N	N	N	Y
ST23: Are there any financing systems in addition to the public drug budget that contribute to the provision of drugs in the public sector?	N	Y	Y	Y	Y	Y
Public sector procurement procedures						
ST24: Are drugs usually procured in the public sector through competitive tender?	Y	N	Y	Y	Y	Y
ST25: Is there a system for monitoring supplier performance?	Y	N	Y	N	Y	Y
ST26: Are tenders done under INN?	Y	Y	Y	Y	Y	Y
ST27: Does the procurement unit receive foreign currency in less than 60 days (from request to release)?	Y	N	(nr)	Y	(nr)	N
ST28: Is procurement in the public sector limited to drugs on the national essential drugs list (EDL)?	N[1]	N	Y[2]	Y	N	N
ST29: Is the average lead time (from order to receipt at central level) less than 8 months?	Y	Y	Y	N	Y	(-) (6-18 months)
ST30: Is procurement based on a reliable quantification of drug needs?	Y	N	Y	N	Y	N

[1] There is no national EDL; to answer this question, the Bulgarian team used the WHO model list.

[2] However, 30% of drugs purchases made by public hospitals with resources from fiscal revenues are not on EDL.

NATIONAL DRUG POLICY - STRUCTURAL INDICATORS

	Bulgaria	Chad	Colombia	Guinea	India Andhra Pradesh	Mali
Public sector distribution and logistics						
ST31: Are good storage practices observed in the central procurement/distribution unit and/or major regional warehouses?	Y[1]	N	Y	Y	N	N
ST32: Is the information recorded on the stockcards for a basket of drugs the same as the quantity of stock in store?	Y[1]	N	Y	N	Y	Y
ST33: Are the stocks for a basket of drugs within their expiry dates in the central procurement/distribution unit and/or major regional warehouses?	Y[1]	Y	Y	Y	Y	N
ST34: Have all incoming products been physically inspected for the last three deliveries in the central procurement/distribution unit and/or in the major regional warehouses?	Y[1]	N	Y	Y	Y	Y
ST35: Are only drugs which are on the national essential drugs list (EDL) in stock in the central procurement/distribution unit and/or in the major regional warehouses?	N[1]	Y	N	Y	N	Y
ST36: Are 80% or more of the vehicles of the central procurement/distribution unit and/or major regional warehouses in working condition?	(nr)	(na)	(nr)	Y	N	N
Pricing policy						
ST37: Are drug prices regulated in the private sector?	Y	Y[2]	N	Y	Y	Y
ST38: Is there at least one major incentive for selling essential drugs at low cost in the private sector?	N	N	Y	N	N	Y
ST39: Is the total margin used by wholesalers and retailers less than 35% of the CIF price?	Y	N	(na)	N	Y	Y (brand) N (INN)

[1] No central or major warehouse exists, but many regional ones; this answer is valid for the vast majority of regional warehouses/stores.

[2] However, regulations are being violated, and there is no control.

NATIONAL DRUG POLICY - STRUCTURAL INDICATORS

	Bulgaria	Chad	Colombia	Guinea	India Andhra Pradesh	Mali
ST40: Is there a system for monitoring drug prices?	Y	N	Y	N	Y	N
ST41: Are essential drugs under INN or generic name sold in private drug outlets?	Y	Y	Y	Y	N	Y
Information and continuing education on drug use						
ST42: Is there a national publication (formulary/ bulletin/manual, etc.), revised within the past five years, providing objective information on drug use?	Y	N[1]	Y	Y	N	Y
ST43: Is there a national therapeutic guide with standardized treatments?	Y	N	N	N	N	Y
ST44: Is the concept of essential drugs part of the curricula in the basic training of health personnel?	N	N	N	N	N	N
ST45: Is there an official continuing education system on rational use of drugs for prescribers and dispensers?	N	N	N	N	N	Y
ST46: Is there a drug information unit/centre?	Y	Y	Y	N	N	N
ST47: Does the drug information unit/centre (or another independent body) provide regular information on drugs to prescribers and dispensers?	Y	N	Y	N	N	N
ST48: Are there therapeutic committees in the major hospitals?	Y	N	N[2]	N	N	N
ST49: Are there public education campaigns on drug use?	(na)	N	Y (not syste-matically)	N	N	Y
ST50: Is drug education included in the primary/secondary school curricula?	N	N	N	N	N	N

[1] A formulary exists for HC level only, but it is not yet distributed countrywide.

[2] In some hospitals yes, but not in all hospitals.

NATIONAL DRUG POLICY - PROCESS INDICATORS*

	'ideal' value**	Bulgaria 1995 (survey1996)	Chad	Colombia '95/'96	Guinea	India Andhra Pradesh	Mali
Legislation and regulation							
PR1: Number of drug outlets inspected, out of total number of drug outlets in the country.	not < 50%	68	0	(-)	0	65	6 (private) < 1 (public)
PR2: Number of drug outlets in violation, out of total number of drug outlets inspected.	0%	27	(0)	(-)	(0)	9	60
PR3: Number of sanctions and administrative measures implemented, out of total number of violations identified.	100%	34	(-)	(-)	(-)	100	100
PR4: Number of samples routinely collected, out of total number of planned collected samples.	100%	(indicator changed)	(-)	(-)	(-)	78	(-) 210 samples collected
PR5: Number of samples tested, out of total number of samples collected.	100%	100	(-)	(-)	100	93	100
PR6: Number of advertisements in violation of regulations on the ethical promotion of drugs, out of total number of advertisements monitored.	0%	(nr)[1]	(-)	(-)	(0)	5	100 (1 case)
PR7: Number of sanctions implemented for advertisements in violation of regulations, out of total number of violations identified.	100%	(nr)[1]	(0)	(-)	(-)	21	100 (1 case)
Essential drug selection and drug registration							
PR8: Value of drugs from the national essential drugs list (EDL) procured in the public sector, out of total value of drugs procured in the same sector.	--> 100%	26	(-)	65	100	85	(-)
PR9: Number of drugs from the national essential drugs list (EDL) prescribed, out of total number of drugs prescribed.	--> 100%	33[2] 70	53 (private) 91 (public)	61 (private) 69 public	28 (private) 87 (public) 39 (market)	39 (private) 98 (public)	26 (private) 56 (public)
PR10: Number of drugs from the national essential drugs list (EDL) sold, out of total number of drugs sold.	--> 100%	40	62 (private)	63	28 (private) 44 (market)	49 (private)	60 (private) 100 (public)

* All Process Indicators are percentages.

** --> 100% = the 'ideal' value should approach 100%, but does not necessarily have to reach 100%.

[1] Regulations just introduced

[2] The first figure is based on drugs included in non reimbursable prescriptions, the 2nd in reimbursable prescriptions.

NATIONAL DRUG POLICY - PROCESS INDICATORS

	'ideal' value	Bulgaria	Chad	Colombia	Guinea	India Andhra Pradesh	Mali
PR11: Number of locally manufactured drugs sold in the country from the national essential drugs list (EDL), out of the total number of drugs from the national essential drugs list.	--> 100%	41	2	95	0 (no local drug production)	100	6
PR12: Number of combination drugs newly registered, out of total number of newly registered drugs.	--> 0%	14	(-) [1]	(-)	33	11	(0) (no new registration)
PR13: Number of registered drugs which are banned in other countries, out of total number of registered drugs.	--> 0%	0.5	(-)	(-)	2	(na)	(0) (no new registration)
Drug allocation in the health budget/public sector financing policy							
PR14: Value of public drug budget spent per capita in the last year, out of average value of the same budget during the past three years.	> 100%	119	(-)	100	89	86	(-)
PR15: Value of public drug budget spent by major hospitals, out of value of public drug budget spent.	not > 40%	37,5	(-)	12	37	76	29
PR16: Value of international aid received for drugs, out of value of public drug budget.	*	0.3	95	(nr)	(na)	0.2	395
PR17: Value of revenue generated for drugs through additional financing system, out of value of public drug budget.	*	0.03	(-)	0-10 [2] 20-60 [2]	(na)	11	(-)
PR18: Public drug budget spent, out of public drug budget allocated.	100%	115	86	(-)	99.8	83	50
Public sector procurement procedures							
PR19: Value of drugs purchased through competitive tender, out of value of drugs purchased.	--> 100%	0,04	0	100	65	100	44
PR20: Value of drugs purchased from local manufacturers through competitive tender, out of value of drugs purchased through competitive tender.	--> 100%	(na)	(-)	(-)	0	100	17

* No ideal value, depends on country situation

[1] No registration yet.

[2] Depending on income level (0-10% for part of population with annual income < 3,500 US$; 20-60% for population with annual income > 3,500 US$).

NATIONAL DRUG POLICY - PROCESS INDICATORS

	'ideal' value	Bulgaria	Chad	Colombia	Guinea	India Andhra Pradesh	Mali
PR21: CIF/ex-factory value of a basket of drugs, out of average CIF/ex-factory value of the same basket the year of reference.	< 100%	181[1]	178 (private) 234 (public) (1995/1993)	100	(na)	114	103
PR22: CIF/ex-factory value of a basket of drugs, out of "reference" value on the international market of the same basket.	< 100%	100	69 (?)	153	119	(na)	(-)
PR23: Average lead time for a sample of orders in the last year, out of average lead time during the past three years.	< 100%	60	(-)	100	(na)	100	(-)
PR24: Average time period of payment for a sample of orders, out of average time period of payment stated in contract.	100%	178	(-)	188	(-)	100	200
PR25: Number of drugs/batches tested, out of number of drugs/batches procured.	100%	100	0	3	0	93	(-)
PR26: Number of drugs/batches that failed quality control testing, out of number of drugs/batches tested.	0%	9.5[2]	(0)	4	(0)	7	(-)
Public sector distribution and logistics							
PR27: Average time between order and delivery from central store to remote facilities in the last year, out of average time between order and delivery in the past three years.	< 100%	33	(-) (14 days)	(-) (10 days)	39	75	(-) (1-6 months)
PR28: Average stockout duration for a basket of drugs in the central and/or regional stores in the last year, out of average stockout duration for the same basket in the past three years.	< 100%	119[3]	(-)	(-)	0	79	(-)
PR29: Average stockout duration for a basket of drugs in a sample of remote facilities in the last year, out of average stockout duration for the same basket in the past three years.	< 100%	125[3]	(-) (59 days)	(-)	294	81	(-)

[1] When comparing 1996 to 1994: 181% - when comparing 1996 to 1995: 114%.
[2] This figure is only for drugs tested on suspicion of non conformity.
[3] Problems linked to the economic crisis rather than lack of management skills.

NATIONAL DRUG POLICY - PROCESS INDICATORS

	'ideal' value	Bulgaria	Chad	Colombia	Guinea	India Andhra Pradesh	Mali
Pricing policy							
PR30: Value of a basket of drugs, out of CIF /ex-factory value of the same basket.	*	139	153 (private) 177 (public)	425	225 (private)	117 (private) 45 (public)	146 (public)
PR31: Average expenditure per prescription, out of average expenditure per prescription in the past three years.	< 100%	(na)	(-) [1]	(-)	103 (pr/CKY)[5] 226 (public)[6]	106 (private) 104 (public)	(-) [7]
PR32: Value of a basket of drugs, out of value of the same basket the year of reference.	< 100%	141 (1996/1994)	156 (private)[2] 192 (public)[2] 161 (market)[2]	100 (1995/1992)	112 (1995/1992)	131 (private) 100 (public)	(-)
Information and continuing education on drug use							
PR33: Number of prescribers having direct access to a (national) drug formulary, out of total number of prescribers surveyed.	100%	25	52(prescribers) 44(dispensers)	50[3]	33(prescribers) 12(dispensers)	21(prescribers)	15.2 (prescribers)
PR34: Number of training sessions on drug use for prescribers in the last year, out of average number of training sessions organized in the past three years.	> 100%	(na)	0		(na)	0	(-)
PR35: Number of prescribers who have attended at least one training session in the last year, out of total number of prescribers surveyed.	100%	0(prescriber) 0(dispenser)	33(prescribers) 36(dispensers)	25[4]	13(prescribers) 15(dispensers)	4 (prescribers)	11 (prescribers)
PR36: Number of issues of independent drug bulletins published in the last year, out of average number of issues of independent drug bulletins published per year in the past three years.	> 100%	205	0	143 (1996/1995)	0	0	50 (1995/1994)
PR37: Average number of copies of independent drug bulletins sent to prescribers, out of total number of prescribers.	not < 100%	11	0	3	(na)		(-)
PR38: Amount spent on public education campaigns on drug use, out of total amount spent on public health education campaigns.	*	(na)	(0)	(na)	(-)		(-)

Note to previous table:

*	No ideal value, depends on country situation
1	Average expenditures are (in USD): 8.7 private; 1.4 public; 4.1 parallel market.
2	1995/1993.
3	More than 50% of prescribers had direct access in 43% of the hospitals assessed.
4	According to the level of care provided in the facility where the prescribers work (1st level 19%, secondary 25% and tertiary 28%).
5	Figure valid for the private sector in the capital (Conakry) only.
6	Average figure. In fact, for drugs authorized at health center level, the indicator is 94% (so a slight decrease in prices).
7	Average expenditure in private sector: 7.2 USD.

NATIONAL DRUG POLICY - OUTCOME INDICATORS*

	'ideal' value	Bulgaria 1996	Chad	Colombia '95/'96	Guinea	India Andhra Pradesh	Mali
Availability of essential drugs							
OT1: Number of drugs from a basket of drugs available in a sample of remote health facilities, out of total number of drugs in the same basket.	100%	85	80	(-)	93	66	(-)
OT2: Number of drugs at the lowest price from a basket of drugs, out of total number of drugs in the same basket.	100%	85	(-)	49	33[4] (private) 46[4] (market)	57	(-)
Affordability of essential drugs							
OT3: Average retail price of standard treatment of pneumonia, out of the average retail price of a basket of food. (NB: basket of food for a family (6-8 persons) for 1 day)	(low)	279[1]	85 (private) 19 (public)	45 (private)[3] 34 (public)	166 (private) 26 (public) 29 (market)	100 (private) 76 (public)	(-)
OT4: Value of a basket of drugs, out of the value of the same basket with the cheapest drugs.	--> 100%	(na)	(-)	183	134 brand 490 INN	169	(-)
Quality of drugs							
OT5: Number of drugs/batches that failed quality control testing, out of the total number of drugs/batches surveyed.	0%	9.6[2]	92 (private) 65 (public)	4	19 (private) 23 (public) 24 (market)	19	(-)
OT6: Number of drugs beyond the expiry date, out of the total number of drugs surveyed.	0%	0	0 (private) 2 (public)	2	0 (private) 0.7 (public) 0 (market)	0	0
Rational use of drugs							
OT7: Average number of drugs per prescription.	1.00-2.00	1.95	1.95 (private) 2.00 (public) 1.88 (market)	2.39	2.08 (private) 2.40 (public) 2.53 (market)	1.93 (private) 2.27 (public)	2,33

* All Outcome Indicators are percentages, except OT7.

1 NB: Basket of food for 1 person, 1 month.

2 Quality testing only in case of suspicion

3 NB: Basket of food for 3-5 persons, 1 month

4 Values for generic drugs; if brand name products are taken, the % available in pharmacies was 69% and in the market 32%.

NATIONAL DRUG POLICY - OUTCOME INDICATORS

	'ideal' value	Bulgaria	Chad	Colombia	Guinea	India Andhra Pradesh	Mali
OT8: Number of prescriptions with at least one injection, out of the total number of prescriptions surveyed.	(low)	9.75	30 (private) 23 (public) 26 (market)	61 (public)[1]	21 (private) 20 (public) 34 (market)	5 (private)[2] 66 (public)	30.7
OT9: Number of children under five with diarrhoea receiving antidiarrhoeal drugs, out of the total number of children under five with diarrhoea surveyed.	--> 0%	(nr)	29	9	15	78	(-)
OT10: Number of drugs from the national essential drugs list (EDL), out of the 50 best selling drugs in the private sector.	100%	46	50	60	26	42	30[3]

1 This figure does not seem to reflect the reality, probably some problems happen when coding or transcribing data.

2 These data should be interpreted with caution as many private doctors administer injections at their clinics and then write prescriptions for drugs to be purchased outside. Consequently, the prescriptions studied at the retail outlet do not capture the injection prescription habits.

3 Out of the 30 best selling drugs.

NATIONAL DRUG POLICY - BACKGROUND INFORMATION

na = not available nr = not relevant

1. COUNTRY INFORMATION:	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
Population data						
BG1: Total population (in millions)	68	17.6	59	72.5 (74.0)[1]	9.3	11.5
BG2: Average annual growth of the population (%)	2.4	1.2	1.98	2.16 (1.86)[1]	3.2	3.14
BG3: Percentage of population living in urban areas (%)	(na)	25 (1990)	23	19.8 (20.2)[1]	42	30.6
BG4: Life expectancy (years)	65	75 F 71 M	69.6	65	55 F 50 M	61
Economic data						
BG5: GNP per capita (USD)	952	588	1650	220 (279.5)[1]	350	438
BG6: Average annual rate of inflation (%)	9.1	11.7	5.8	14.4	40	22.5
2. HEALTH INFORMATION:	**Philippines**	**Sri Lanka**	**Thailand**	**Viet Nam**	**Zambia**	**Zimbabwe**
Health status data						
BG7: Infant mortality rate (per 1000)	56	17.2	25.95	46	123.3	61
BG8: Maternal mortality rate (per 100,000)	80	30	14		220	395

[1] Figures for 1995.

NATIONAL DRUG POLICY - BACKGROUND INFORMATION

	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
Health system data						
BG13: Total number of prescribers	483,275	6,127	13,629[1]	63,947		15,819
BG14: Total public health budget (million USD)	308 (1993)	151	1,985.4	168 (228.5)[4]		143[2]
BG15: Total value of international aid for the health sector (million USD)	69 (1990)	3	14.25	35.8 (47.4)[4]		39[2]
BG16: Total health expenditure (million USD)	870 (1991)		5,938.2	231 (323)[4]		...
3. DRUG SECTOR INFORMATION:	**Philippines**	**Sri Lanka**	**Thailand**	**Viet Nam**	**Zambia**	**Zimbabwe**
Economic data						
BG17: Total public drug expenditure (million USD)	41 (1993)	23.5	93.1[5]	33.6 (64.6)[4]		51.6[2]
BG18: Total value of international aid for drugs (cash + kind) (million USD)	(na)	0.5	(na)	7.2 (9.6)[4]		9.25[2/3]
BG19: Total drug expenditure (public + households + international aid) (million USD)	888 (1993)		2,000	239 (266)[4]		89.94[2]
BG20: Total value of local production (ex-factory price) sold in the country (million USD)	(na)	5.5 (1994)	481.3	87		42.6[2]
BG21: Total value of drug imports (CIF) (million USD)	171 (1992)	50 (1992)	187.3	152		44.7[2]

1 Medical doctors. Data from government published statistics, but likely to be underestimated.
2 Fiscal year 1994/1995.
3 Figure for fiscal year 1995/1996 is 20.56 million US dollars.
4 Figures for 1995.
5 Hospitals under Ministry of Public Health only.

NATIONAL DRUG POLICY - BACKGROUND INFORMATION

	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
BG22: Total value of drugs under generic name (CIF and ex-factory prices) sold in the country (million USD)	84.6 (1994)		(nr)	(na)		59.93[3]
Human resources						
BG23: Total number of pharmacists	1,498	3,966	4,721[4]	7,500	101	485
BG24: Total number of pharmacy technicians or other aides/assistants	(na)	643	(na)	16,376	200 (estimation)	224
Drug sector organization						
BG25: Total number of drug manufacturing units in the country	244	12	177	84	7	20
BG26: Total number of wholesalers in the country	693	150	(496 importers)	132	47	35
BG27: Total number of pharmacies and drug outlets in the public sector (including health facilities and hospitals that dispense drugs)	363	922	9,648	22,400[1]	877	1,037
BG28: Total number of pharmacies and drug outlets in the private sector	9,985	1,541	23,842	4,300 (ph'cy) 15,000(outl.)	288 36 (ph'cies)	922
BG29: Total number of private pharmacies and drug outlets in the three major urban areas	3,513	673	(na)	3,100	[2]	429
Number of drugs						
BG30: Total number of registered drugs (in dosage forms and strengths)	15,050 (6,377 brands)	5,550	29,461	6,000	750	2,235 (1,135 INN)
BG31: Total number of drugs on the national essential drugs list (in dosage forms and strengths)	(536 INN)	350	389	188	354	592

[1] Includes all kind of public drug outlets.
[2] Almost all private pharmacies are in urban areas.
[3] Fiscal year 1994/1995.
[4] Data from government published statistics, but likely to be underestimated.

NATIONAL DRUG POLICY - STRUCTURAL INDICATORS

	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
Legislation and regulation						
ST1: Is there an official national drug policy document updated in the past ten years?	Y	N	Y	N (94) Y (95)	N	Y
ST2: Is there drug legislation updated in the past ten years?	Y	N	Y	Y	N	Y
ST3: Have regulations based on the drug legislation been issued?	Y	Y	Y	Y	N	Y
ST4: Is there a drug regulatory authority whose mandate includes registration and inspection?	Y	Y	Y	Y	Y	Y
ST5: Is there a licensing system to regulate the sale of drugs (wholesalers, pharmacists, retailers)?	Y	Y	Y	Y	Y	Y
ST6: Are pharmacists legally entitled to substitute generic drugs for brand name products?	Y	N	N	N	N[1]	Y
ST7: Are there legal provisions for penal sanctions?	Y	Y	Y	Y	Y (but low)	Y
ST8: Is there a check-list for carrying out inspections in different types of pharmaceutical establishments?	Y	N	Y	N	Y	Y
ST9: Are there any institutions within or outside the country where quality control is carried out?	Y	Y	Y	Y	Y	Y
ST10: Is the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce used systematically?	N	Y	N	N	Y	N
ST11: Are there controls on drug promotion based on regulations and consistent with the WHO ethical criteria for medicinal drug promotion?	N	Y	Y	N (94) Y (95)	N	Y

[1] The Draft Act is silent on this issue; at the University Teaching Hospital pharmacists are allowed to issue generics when a brand name is prescribed.

NATIONAL DRUG POLICY - STRUCTURAL INDICATORS

	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
Essential drug selection and drug registration						
ST12: Is there a national essential drugs list (EDL)/formulary using INN officially adopted and distributed countrywide?	Y	Y	Y	Y	Y	Y
ST13: Is there an official drug committee whose duties include updating the national essential drugs list (EDL)?	Y	N	Y	N (94) Y (95)	Y	Y
ST14: Has the national essential drugs list (EDL)/formulary been updated and distributed countrywide in the past five years?	Y	Y	Y	N (94) Y (95)	N	Y
ST15: Is it mandatory that drug donations comply with the national essential drugs list (EDL)?	N	N	N	N	N	Y
ST16: Are there formal procedures for registering drugs?	Y	Y	Y	Y	Y	Y
ST17: Is there a drug registration committee?	N[1]	Y	Y	Y	Y[2]	Y
ST18: Is drug registration renewal required at least every five years?	Y	Y	N	Y	N (but annual retention fee)	Y
Drug allocation in the health budget/public sector financing policy						
ST19: Is the public drug expenditure more than 20% of the MOH operating budget spent per year for the last three years?	N	N	Y	N	N	Y
ST20: Is the public drug expenditure per capita more than US$1.00 per year for the last three years?	N	Y	Y	N	N	Y

[1] No specific committee but a well-organized procedure conducted by BFAD.

[2] No specific committee; the secretariat of the Pharmacy, Medicine and Poisons Board is taking on this function.

NATIONAL DRUG POLICY - STRUCTURAL INDICATORS

	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
ST21: Is the percentage of the public drug expenditure for national hospitals less than 40% for the last three years?	(na)	Y	Y	N		Y
ST22: Has the public drug expenditure per capita increased in the last three years?	(na)	Y	Y	Y	N	Y/N[4]
ST23: Are there any financing systems in addition to the public drug budget that contribute to the provision of drugs in the public sector?	Y	N	Y	Y	N	N
Public sector procurement procedures						
ST24: Are drugs usually procured in the public sector through competitive tender?	Y	Y	Y[1]	N	Y	Y
ST25: Is there a system for monitoring supplier performance?	N	Y	Y	N	Y (partly)	N
ST26: Are tenders done under INN?	Y	Y	Y	N	Y	Y
ST27: Does the procurement unit receive foreign currency in less than 60 days (from request to release)?	(nr)	Y	(nr)	Y	N	Y
ST28: Is procurement in the public sector limited to drugs on the national essential drugs list (EDL)?	Y	N	N	N	Y	Y
ST29: Is the average lead time (from order to receipt at central level) less than 8 months?	Y	N	(nr)	Y	N	Y
ST30: Is procurement based on a reliable quantification of drug needs?	N	Y	Y/N[2]	N	Y/N[3]	N

1 Only when the value exceeds 2000 US dollars.

2 Practices vary in different hospitals.

3 There is a model to calculate drug needs based on consumption figures, but due to insufficient funds the calculated figures have to be reduced, which is often done on an 'ad hoc' basis.

4 It went up, then down.

NATIONAL DRUG POLICY - STRUCTURAL INDICATORS

	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
Public sector distribution and logistics						
ST31: Are good storage practices observed in the central procurement/distribution unit and/or major regional warehouses?	Y	N	Y/N[1]	N Y (central)	Y	59%
ST32: Is the information recorded on the stockcards for a basket of drugs the same as the quantity of stock in store?	Y		Y/N[1]	Y		88%
ST33: Are the stocks for a basket of drugs within their expiry dates in the central procurement/distribution unit and/or major regional warehouses?	Y		Y/N[1]	Y		Y
ST34: Have all incoming products been physically inspected for the last three deliveries in the central procurement/distribution unit and/or in the major regional warehouses?	(na)	N	Y/N[1]	N	Y	Y
ST35: Are only drugs which are on the national essential drugs list (EDL) in stock in the central procurement/distribution unit and/or in the major regional warehouses?	Y	N	Y	Y		Y
ST36: Are 80% or more of the vehicles of the central procurement/distribution unit and/or major regional warehouses in working condition?	(nr)		Y	Y	Y	Y
Pricing policy						
ST37: Are drug prices regulated in the private sector?	N	Y	N	N	N	N
ST38: Is there at least one major incentive for selling essential drugs at low cost in the private sector?	N	N	N	N	N	(Y)[2]
ST39: Is the total margin used by wholesalers and retailers less than 35% of the CIF price?	(na)	Y	N	N	N[2]	N

[1] Individual hospitals usually purchase directly from manufacturers/importers; for most individual hospitals the answer is 'no'.

NATIONAL DRUG POLICY - STRUCTURAL INDICATORS

	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
ST40: Is there a system for monitoring drug prices?	Y	N	N	N	N	Y
ST41: Are essential drugs under INN or generic name sold in private drug outlets?	Y	Y	Y	Y	Y[1]	Y
Information and continuing education on drug use						
ST42: Is there a national publication (formulary/ bulletin/manual, etc.), revised within the past five years, providing objective information on drug use?	Y	Y	Y	Y	Y	N
ST43: Is there a national therapeutic guide with standardized treatments?	Y	Y	Y	Y	Y (partly)	Y
ST44: Is the concept of essential drugs part of the curricula in the basic training of health personnel?	N (starting to do this)	Y	Y	N		Y
ST45: Is there an official continuing education system on rational use of drugs for prescribers and dispensers?	N	N	Y	N	N	N
ST46: Is there a drug information unit/centre?	Y	N	Y	Y	N	Y
ST47: Does the drug information unit/centre (or another independent body) provide regular information on drugs to prescribers and dispensers?	N	N	Y	N	N	N
ST48: Are there therapeutic committees in the major hospitals?	Y	Y	Y	Y	Y[2]	N
ST49: Are there public education campaigns on drug use?	Y	N	Y	N (94) Y (95) (on antibiotics only)	N[3]	Y[2]
ST50: Is drug education included in the primary/secondary school curricula?	N	N	Y	N		N

[1] Although there is no specific policy on this. [2] In process. [3] Partly.

NATIONAL DRUG POLICY - PROCESS INDICATORS*

	'ideal' value**	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
Legislation and regulation							
PR1: Number of drug outlets inspected, out of total number of drug outlets in the country.	not < 50%	110 (NCR)	100	59.8	27.5		15
PR2: Number of drug outlets in violation, out of total number of drug outlets inspected.	0%	10	35	7.6	84.2		36
PR3: Number of sanctions and administrative measures implemented, out of total number of violations identified.	100%	7	17.5	23.3	65.5	(3 licences revoked '94)	16
PR4: Number of samples routinely collected, out of total number of planned collected samples.	100%	(-) (3,758 samples collected)		45.9	79		(nr)
PR5: Number of samples tested, out of total number of samples collected.	100%	93		60.4	92.1		(-) (153 samples tested)
PR6: Number of advertisements in violation of regulations on the ethical promotion of drugs, out of total number of advertisements monitored.	0%	3		2.5	(na)		36
PR7: Number of sanctions implemented for advertisements in violation of regulations, out of total number of violations identified.	100%	100		23.3	(na)		33
Essential drug selection and drug registration							
PR8: Value of drugs from the national essential drugs list (EDL) procured in the public sector, out of total value of drugs procured in the same sector.	--> 100%	100	69	53.3	40 (estimation)	100	100[2]
PR9: Number of drugs from the national essential drugs list (EDL) prescribed, out of total number of drugs prescribed.	--> 100%	79 (private) 91 (public)		76.8[1] (public)	36.2 (priv.) 40.5 (pub)		70 (private) 99 (public)
PR10: Number of drugs from the national essential drugs list (EDL) sold, out of total number of drugs sold.	--> 100%	77	50.4	42.1	33.3	69 (private) 80 (public)	(-)

Note to previous table:

* All Process Indicators are percentages.

** --> 100% = the 'ideal' value should approach 100%, but does not necessarily have to reach 100%.

1 Data from 2 hospitals.

2 GMS procures only from EDL; Hospitals can procure other drugs; figures are not available, but % non-EDL drugs is expected to be small.

NATIONAL DRUG POLICY - PROCESS INDICATORS

	'ideal' value	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
PR11: Number of locally manufactured drugs sold in the country from the national essential drugs list (EDL), out of the total number of drugs from the national essential drugs list.	--> 100%	(nr)	17	(na)	56.9		53
PR12: Number of combination drugs newly registered, out of total number of newly registered drugs.	--> 0%	5	16.2	14.2	25.7		22
PR13: Number of registered drugs which are banned in other countries, out of total number of registered drugs.	--> 0%	4			(na)		0
Drug allocation in the health budget/public sector financing policy							
PR14: Value of public drug budget spent per capita in the last year, out of average value of the same budget during the past three years.	> 100%	(na)	126	(na)	184		100
PR15: Value of public drug budget spent by major hospitals, out of value of public drug budget spent.	not > 40%		35	(na)	90.7		21
PR16: Value of international aid received for drugs, out of value of public drug budget.	(-)	(-)	2	(na)	20.4		17.9
PR17: Value of revenue generated for drugs through additional financing system, out of value of public drug budget.	(-)			(na)	42.8	[1]	2.9
PR18: Public drug budget spent, out of public drug budget allocated.	100%	100	100	(na)	100		144
Public sector procurement procedures							
PR19: Value of drugs purchased through competitive tender, out of value of drugs purchased.	--> 100%	100	100	100	...		53.7
PR20: Value of drugs purchased from local manufacturers through competitive tender, out of value of drugs purchased through competitive tender.	--> 100%	(nr)	< 20 (estimation)	(nr)	(nr) (no tender)		68[2]

[1] A cost recovery system exists; its total value is < 1% of the total public health budget.

[2] Estimation; this figure was calculated for 1992 (65%), and is believed to have remained about the same.

NATIONAL DRUG POLICY - PROCESS INDICATORS

	'ideal' value	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
PR21: CIF/ex-factory value of a basket of drugs, out of average CIF/ex-factory value of the same basket the year of reference.	< 100%	(-)		(na)	(na)		110
PR22: CIF/ex-factory value of a basket of drugs, out of "reference" value on the international market of the same basket.	< 100%	(-)		(na)	(na)		100
PR23: Average lead time for a sample of orders in the last year, out of average lead time during the past three years.	< 100%	(-)		(na)	33.3		98
PR24: Average time period of payment for a sample of orders, out of average time period of payment stated in contract.	100%	(-)		(na)	133		150
PR25: Number of drugs/batches tested, out of number of drugs/batches procured.	100%	95		27	14.26	0	7.7
PR26: Number of drugs/batches that failed quality control testing, out of number of drugs/batches tested.	0%	1.5	22[1]	23.5	0		10
Public sector distribution and logistics							
PR27: Average time between order and delivery from central store to remote facilities in the last year, out of average time between order and delivery in the past three years.	< 100%	(-) (12 days in 1995)	99	(excluded)	(-) (4.8 days)	[2]	115
PR28: Average stockout duration for a basket of drugs in the central and/or regional stores in the last year, out of average stockout duration for the same drug basket in the past three years.	< 100%	(-)		(excluded)	(na)	60 MSL [3] 2 OMS [3]	(-) (24.5 days)
PR29: Average stockout duration for a basket of drugs in a sample of remote facilities in the last year, out of average stockout duration for the same drug basket in the past three years.	< 100%	(-) (173 days in 1995)		(excluded)	(-) (2.6 days)		(-)

[1] Average figure; 32% of 'complaint-samples' and 13% of randomly collected samples failed.
[2] Drug kits are delivered automatically, without order.
[3] MSL = Medical Stores Limited; OMS = Old Medical Stores.

NATIONAL DRUG POLICY - PROCESS INDICATORS

	'ideal' value	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
Pricing policy							
PR30: Value of a basket of drugs, out of CIF /ex-factory value of the same basket.	(-)	(-)	165 (CIF)	(excluded)	(na)		213 (private) 115 (public)
PR31: Average expenditure per prescription, out of average expenditure per prescription in the past three years.	< 100%	(-) [1]		(excluded)	95.6 (private) 96.6 (public)		110 (private) 101 (public)
PR32: Value of a basket of drugs, out of value of the same basket the year of reference.	< 100%	(-)		(excluded).	98.4 (private) 122.2 (public)		112 (private) 110 (public)
Information and continuing education on drug use							
PR33: Number of prescribers having direct access to a (national) drug formulary, out of total number of prescribers surveyed.	100%	42	3	(excluded)	31.5 82.5 (95)	41.3	91
PR34: Number of training sessions on drug use for prescribers in the last year, out of average number of training sessions organized in the past three years.	> 100%	(-)		(na)	360		300
PR35: Number of prescribers who have attended at least one training session in the last year, out of total number of prescribers surveyed.	100%	27	21	(excluded)	69.5	29	5(prescribers) 56(dispensers)
PR36: Number of issues of independent drug bulletins published per year, out of average number of issues of independent drug bulletins published per year in the past three years.	> 100%	200	120	(excluded).	154.5		40 (Pharmanews)
PR37: Number of copies of independent drug bulletins sent to prescribers, out of total number of prescribers.	not < 100%	35	95	(excluded)	78.5		25 (Pharmanews)
PR38: Amount spent on public education campaigns on drug use, out of total amount spent on public health education campaigns.	(-)-	(-)		(na)	6		3

[1] Average expenditure per prescription in 1995: private sector = 5.81 USD, public sector = 3.75 USD.

NATIONAL DRUG POLICY - OUTCOME INDICATORS*

	'ideal' value	Philippines	Sri Lanka	Thailand	Viet Nam	Zambia	Zimbabwe
Availability of essential drugs							
OT1: Number of drugs from a basket of drugs available in a sample of remote health facilities, out of total number of drugs in the same basket.	100%	54	100	(excluded)	80.5	54.8	70
OT2: Number of drugs at the lowest price from a basket of drugs, out of total number of drugs in the same basket.	100%	66		(excluded)	53	17	64
Affordability of essential drugs							
OT3: Average retail price of standard treatment of pneumonia, out of the average retail price of a basket of food. (NB: basket of food for a family (6-8 persons) for 1 day)	low	16 (private) 9 (public)		(excluded)	188.6(private)[5] 179.5 (public)		38 (private) 28 (public)
OT4: Value of a basket of drugs, out of the value of the same basket with the cheapest drugs.	--> 100%	(-)		(excluded)	262	179[6]	135
Quality of drugs							
OT5: Number of drugs/batches that failed quality control testing, out of the total number of drugs/batches surveyed.	0%	5	13	21.8	25		10
OT6: Number of drugs beyond the expiry date, out of the total number of drugs surveyed.	0%	0		(excluded)	0.16	0 (private) 2 (public)	3
Rational use of drugs							
OT7: Average number of drugs per prescription.	1.00-2.00	2.63 (private) 1.73 (public)	1.92 (private) (data partly analysed)	3.05[4]	4.3 (private) 4.5 (public)	2.0 (pr.clin.) 1.5 (pr.outlet) 2.3 (public)	1.72(private) 1.65 (public) 1.80 (RHC)[1]
OT8: Number of prescriptions with at least one injection, out of the total number of prescriptions surveyed.	low	12 (private) 6 (public)	1[2]	2.6[4]	17.3 (private) 31.9 (public)	24 (pr.clin.) 9.6 (pr.outlet) 20 (public)	3 (private) 13 (public)
OT9: Number of children under five with diarrhoea receiving antidiarrhoeal drugs, out of the total number of children under five with diarrhoea surveyed.	--> 0%	0.4 (private) 2.96 (public)	0[3]	95.5[8]	10.5	58 (pr.clin.)[7] 54 (pr.outlet) 30 (public)	(-)
OT10: Number of drugs from the national essential drugs list (EDL), out of the 50 best selling drugs in the private sector.	100%	52		(excluded)	78	94	50

Note to the previous table:

* All Outcome Indicators are percentages, except OT7.

1 RHC = rural health center (public sector).

2 Data partly analysed; injections often provided directly by prescriber, and therefore 'not prescribed'.

3 No paediatric antidiarrhoeal drugs in the market.

4 Data from 2 provincial hospitals.

5 The average retail price of a basket of food is calculated in Viet Nam for one person/day.

6 Provisional figure; the importance of the different drugs in the basket has not yet been taken into account.

7 pr.clin. = private clinic/dispensary; pr.outlet = private drug outlet; public = public drug outlet.

8 Private drugstores only.

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